OSTEOPOROSIS CARE GAP

A Thesis
Submitted to the Faculty of Graduate Studies and Research
In Partial Fulfillment of the Requirements
For the Degree of

Special Case Doctor of Philosophy
in
Kinesiology and Health Studies
University of Regina

By
Katherine M. McLeod
Regina, Saskatchewan
August, 2013

Copyright 2013: K.M. McLeod
Katherine Margaret McLeod, candidate for the degree of Special Case Doctor of Philosophy in Kinesiology & Health Studies, has presented a thesis titled, *Osteoporosis Care Gap*, in an oral examination held on July 4, 2013. The following committee members have found the thesis acceptable in form and content, and that the candidate demonstrated satisfactory knowledge of the subject material.

External Examiner: Dr. Susan Whiting, University of Saskatchewan
Supervisor: Dr. Shanthi Johnson, Faculty of Kinesiology & Health Studies
Committee Member: Dr. Mary Hampton, Department of Psychology
Committee Member: Dr. Patrick Neary, Faculty of Kinesiology & Health Studies
Committee Member: Dr. Marlene Smadu, Adjunct

Chair of Defense: Dr. Richard MacLennan, Department of Psychology

*Not present at defense*
ABSTRACT

Osteoporosis and its related fractures pose a major public health concern and a considerable economic burden on health care systems. There are recognized gaps, not only in care between best practice and actual care delivery as it relates to osteoporosis screening access, but also from knowledge to practice as men and women at risk of osteoporosis and fragility fractures are not engaging in adequate preventive health behaviours. A series of three studies were conducted and emphasized primary and secondary prevention of osteoporosis in effort to reduce the care gap.

The purpose of Study 1 was to conduct a systematic review to identify common validated clinical risk factor assessment tools in predicting low BMD in postmenopausal women and identify which tool demonstrated the best discriminative performance. A comprehensive literature review of published data in multiple databases was performed based on standardized inclusion and exclusion criteria. Based on 22 primary articles, two independent reviewers identified six risk factor assessment tools. The OST was the simplest tool to determine postmenopausal women at increased risk of osteoporosis who would benefit from DXA screening, while still maintaining acceptable discriminatory abilities. Results of this study were used to inform Study 2.

The purpose of Study 2 was to evaluate the accuracy of calcaneal QUS and OST in identifying men and women over 50 years of age with osteoporosis as defined by DXA, and to establish optimal cut-offs to determine risk. This study \(N = 202, M_{\text{age}} = 59.7\) years) assessed BMD of the lumbar spine and femoral neck using DXA and subsequent calcaneal QUS and OST assessment. Pearson’s product correlation coefficients between QUS and DXA parameters were calculated. ROC analyses were
performed and optimal thresholds for QUS were defined based on sensitivity, specificity, and likelihood ratio analysis. Results showed QUS at the femoral neck in women consistently out-performed QUS at the lumbar spine and OST in men and women. QUS SI cut-off values that fall between 65 and 78 would warrant DXA screening, with a cut-off < 65 indicating high likelihood of osteoporosis.

The purpose of Study 3 was to determine the influence of DXA screening combined with theory-based osteoporosis education versus usual care (DXA screening alone) on change in men and women’s health behaviours, specifically calcium and vitamin D intake, physical activity, and drug treatment initiation. A 6-month RCT was conducted in 203 men and women ($M_{\text{age}} = 59.7$ years) referred by an HCP to undergo DXA screening for the first time. Participants were randomly assigned to an intervention group ($n = 102$) or usual care group ($n = 101$) and completed a series of questionnaires. The intervention group received osteoporosis education, using the Health Belief Model as a theoretical framework. Results showed the intervention increased calcium and vitamin D intake and physical activity compared to DXA screening alone. Multivariate logistic regression analyses showed the intervention was an independent predictor of calcium intake, and DXA screening results indicating low BMD independently predicted drug treatment initiation.

Overall, the series of studies provided valuable insight for practical solutions regarding improved detection of osteoporosis and informing health promotion programs for prevention and management of the disease. It is evident there is an overall need for studies evaluating osteoporosis detection, prevention, and management in older men.
ACKNOWLEDGEMENT

Many people have contributed their time, knowledge, and support to this dissertation. First and foremost, I would like to express my sincerest thanks to my advisor and mentor, Dr. Shanthi Johnson. You have played an integral role in my success. You have taught me how to effectively set, and meet my goals, and have continuously encouraged me to strive to become a better researcher and well-rounded academic. I greatly value your dedicated support, advice, and continuous guidance over the years, and will in the years to come.

I am also grateful for the insight and encouragement that I received from my committee members, Dr. Patrick Neary, Dr. Marlene Smadu, and Dr. Mary Hampton. Your collective expertise was invaluable to this dissertation, and your questions have encouraged me to think beyond the details of my work.

I would also like to thank Dr. Harold Reimer for providing me with lecturer opportunities, and the Faculty of Kinesiology and Health Studies staff who have provided a welcoming environment and whom I relied on regularly. Thank you to my fellow graduate students along the way who have been so supportive, and many with whom I have developed close friendships that will last long after graduate school. Last, a special thanks to technicians and radiologists at the Regina General Hospital who played a major role in recruitment for my study, as well as my participants, and research assistants.

This research was supported by Canadian Institute of Health Research (CIHR) Doctoral Research Award in Partnership with the Saskatchewan Health Research Foundation, Saskatchewan Health Research Foundation, Faculty of Graduate Studies and Research, and the SGI Graduate Fellowship in Aging and Health.
DEDICATION

This dissertation is dedicated to my father and mother, Dr. William and Martha (Muffy) McLeod. I would not be writing these words without their loving support, belief, sheer patience, and encouragement throughout all aspects of my academic pursuits. To my mother, your intelligence, eloquence, sincerity, and sensibility have played a major role in my success and who I am today. You have encouraged me to take on all the wonderful opportunities that have come my way and have remained my biggest cheerleader. To my father, thank you for always teaching me that education and learning are vital to my growth and success. You will always be my example of determination, wisdom, and strength. I am not afraid of working hard, of questioning myself, of striving to be better every day because of you. To my sisters, Ann and Emily, on the best days and most difficult of days, you have always been there with supporting words, a good laugh, and unbeknownst to you, have reminded me of the importance of balance in my life.

May I fully use the blessings and responsibilities that this PhD entrusts to me.
# TABLE OF CONTENTS

ABSTRACT .............................................................................................................I

ACKNOWLEDGEMENT ..........................................................................................III

DEDICATION ...........................................................................................................IV

TABLE OF CONTENTS ............................................................................................V

LIST OF TABLES ......................................................................................................X

LIST OF FIGURES ..................................................................................................XII

LIST OF APPENDICES ............................................................................................XIII

LIST OF ABBREVIATIONS .......................................................................................XIV

OVERVIEW OF THESIS ORGANIZATION ..............................................................1

CHAPTER 1: INTRODUCTION .................................................................................2

1.1 Prevalence of Osteoporosis and Related Fracture in Canada .......................2

1.2 The Osteoporosis Care Gap in Canada .............................................................3

1.3 Research Objectives ..........................................................................................7

1.4 Research Significance to the Osteoporosis Care Gap ....................................7

CHAPTER 2: LITERATURE REVIEW AND THEORETICAL FRAMEWORK ..........9

2.1 Epidemiology of Osteoporosis and Related Fractures ..................................9

2.1.1 Clinical Consequences .................................................................................10

2.1.2 Economic Burden .......................................................................................12

2.2 Classification and Pathophysiology of Osteoporosis ....................................13

2.2.1 Bone Architecture ......................................................................................13

2.2.2 Bone Remodelling ....................................................................................15

2.2.3 Biochemical Markers of Bone Turnover ....................................................19
2.2.4 Classification of Osteoporosis .................................................. 20

2.3 Prevention and Management of Osteoporosis .............................. 20
   2.3.1 Risk Factors for Low Bone Mineral Density ......................... 20
   2.3.2 Calcium and Vitamin D Intake ......................................... 25
   2.3.3 Physical Activity ..................................................... 33
   2.3.4 Drug Treatment ...................................................... 38

2.4 Detection of Osteoporosis: Screening and Diagnosis ...................... 44
   2.4.1 Dual Energy X-ray Absorptiometry (DXA) .......................... 45
   2.4.2 Quantitative Calcaneal Ultrasound ................................ 53
   2.4.3 Clinical Risk Factor Screening Tools ................................. 56
   2.4.4 Ethical Implications of Screening ................................... 62

2.5 Influence of DXA Screening on Health Behaviours ......................... 65
   2.5.1 Change in Calcium and Vitamin D Intake .......................... 66
   2.5.2 Change in Physical Activity ....................................... 69
   2.5.3 Initiation of Drug Treatment ....................................... 71

2.6 Osteoporosis Education and Theoretical Framework ....................... 75
   2.6.1 Theoretical Framework: The Revised Health Belief Model (RHBM) of
        Behavioural Change .................................................... 75
   2.6.2 Measurements of the Revised Health Belief Model Constructs .... 80
   2.6.3 Osteoporosis Health Beliefs in Men and Women .................. 81
   2.6.4 Relationship between Osteoporosis Health Beliefs and Health
        Behaviour ................................................................. 83
   2.6.5 Osteoporosis Education Interventions ................................ 84

VI
2.6.6 Influence of Osteoporosis Education Combined with DXA Screening on Health Behaviours..................................................................................88

CHAPTER 3: STUDY OBJECTIVES.................................................................................................................................93

3.1 Study Objectives and Hypotheses.............................................................................................................................93

3.1.1 Study 1 Objective..................................................................................................................................................94

3.1.2 Study 2 Objective..................................................................................................................................................94

3.1.3 Study 3 Objective..................................................................................................................................................95

3.2 Structure of Thesis Results.........................................................................................................................................96

CHAPTER 4: STUDY 1.........................................................................................................................................................98

4.1 Introduction...............................................................................................................................................................99

4.2 Methods....................................................................................................................................................................100

4.3 Results.......................................................................................................................................................................104

4.4 Discussion..................................................................................................................................................................114

4.5 Conclusion...............................................................................................................................................................117

CHAPTER 5: STUDY 2.........................................................................................................................................................118

5.1 Introduction...............................................................................................................................................................119

5.1.1 Calcaneal Quantitative Ultrasound..................................................................................................................121

5.1.2 Osteoporosis Self-Assessment Tool..................................................................................................................122

5.2 Methods....................................................................................................................................................................124

5.2.1 Participants............................................................................................................................................................124

5.2.2 Recruitment and Screening Procedures.............................................................................................................125

5.2.3 Study Design and Procedure...............................................................................................................................127

5.2.4 Ethical Considerations.........................................................................................................................................128
6.2.6.2 Follow-up..........................................................................................181

6.2.7 Outcome Measures..................................................................................182

6.2.7.1 Background Health History Questionnaire............................................182

6.2.7.2 3-Day Food Record..................................................................................183

6.2.7.3 Modified Baecke Physical Activity Questionnaire...............................183

6.2.7.4 Anthropometric Measurements...........................................................184

6.2.7.5 Follow-Up Questionnaire......................................................................184

6.3 Study Power.................................................................................................185

6.4 Statistical Analysis.......................................................................................185

6.4.1 Logistic Regression Model Diagnostics......................................................186

6.4.1.1 Univariate Logistic Regression Analyses...............................................189

6.4.1.2 Multivariate Logistic Regression Analyses..........................................190

6.5 Results..........................................................................................................193

6.6 Discussion.....................................................................................................221

6.6.1 Impact of Theory-based Osteoporosis Education.....................................222

6.6.2 Change in Calcium Intake........................................................................226

6.6.3 Change in Vitamin D Intake.....................................................................228

6.6.4 Change in Physical Activity......................................................................229

6.6.5 Osteoporosis Drug Treatment Initiation....................................................230

6.6.6 Strengths and Limitations.........................................................................233

6.7 Conclusion.....................................................................................................237

CHAPTER 7: CONCLUSIONS AND FUTURE DIRECTIONS.................................239

REFERENCES..................................................................................................243
LIST OF TABLES

Table 1  Risk factor indicators for measuring BMD by DXA……………………22
Table 2  Algorithm and threshold value for the Osteoporosis Self-Assessment Tool
            (OST).......................................................................................................59
Table 3  Algorithm and Cut-off Values for Osteoporosis Clinical Risk Factor
            Assessment Tools........................................................................................105
Table 4  Efficacy of Osteoporosis Clinical Risk Factor Assessment Tools.........111
Table 5  Diagnostic Accuracy Outcomes Based on DXA Result.......................148
Table 6  Descriptive Characteristics and Results of DXA, QUS, and OST
            Measurements of the Study Population......................................................152
Table 7  Correlation Coefficients of DXA T-score, QUS parameters, and OST...155
Table 8  Area Under the Receiver Operating Characteristic Curves (AUC) for QUS
            and OST to Identify DXA T-score ≤ -2.5 in Men and Women………………158
Table 9  Sensitivity, Specificity, and Positive Likelihood Ratio of QUS at Pertinent
            Cut-offs to Identify DXA T-score ≤ -2.5 at the Femoral Neck and Lumbar
            Spine in Women.................................................................166
Table 10 Sensitivity, Specificity, and Positive Likelihood Ratio of OST at Pertinent
            Cut-offs to Identify DXA T-score ≤ -2.5 at the Femoral Neck and Lumbar
            Spine in Women.................................................................167
Table 11 Sensitivity, Specificity, and Positive Likelihood Ratio of QUS at Pertinent
            Cut-offs to Identify DXA T-score ≤ -2.5 at the Femoral Neck and Lumbar
            Spine in Men.................................................................170
<p>| Table 12 | Sensitivity, Specificity, and Positive Likelihood Ratio of OST at Pertinent Cut-offs to Identify DXA T-score ≤ -2.5 at the Femoral Neck and Lumbar Spine in Men | 171 |
| Table 13 | Correlation Coefficients | 203 |
| Table 14 | Baseline Characteristics of Participants by Group | 210 |
| Table 15 | Calcium and Vitamin D Intake and Physical Activity at Baseline and 6-month Follow-up By Group | 214 |
| Table 16 | Calcium and Vitamin D Intake, Physical Activity, and Drug Treatment Initiation at Follow-up by Group | 216 |
| Table 17 | Descriptive Statistics and Univariate Predictors of Change in Calcium Intake | 218 |
| Table 18 | Multivariate Predictors of Change in Calcium Intake | 221 |
| Table 19 | Descriptive Statistics and Univariate Predictors of Change in Vitamin D Intake | 223 |
| Table 20 | Multivariate Predictors of Change in Vitamin D Intake | 226 |
| Table 21 | Descriptive Statistics and Univariate Predictors of Change in Physical Activity | 228 |
| Table 22 | Multivariate Predictors of Change in Physical Activity | 231 |
| Table 23 | Descriptive Statistics and Univariate Predictors of Osteoporosis Drug Treatment Initiation in Participants who discussed their DXA Results with a Health Care Provider (n = 103) | 233 |
| Table 24 | Multivariate Predictors of Osteoporosis Drug Treatment Initiation | 235 |</p>
<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1</td>
<td>Schematic diagram of bone remodelling and the role of osteoclasts and osteoblasts</td>
<td>18</td>
</tr>
<tr>
<td>Figure 2</td>
<td>Flowchart of mechanisms leading to low bone mineral density and fracture by calcium and vitamin D deficiency</td>
<td>27</td>
</tr>
<tr>
<td>Figure 3</td>
<td>Adaptation of the Revised Health Belief Model constructs and linkages for taking vitamin D supplements</td>
<td>78</td>
</tr>
<tr>
<td>Figure 4</td>
<td>Flowchart summarizing the systematic review search process and study identification</td>
<td>103</td>
</tr>
<tr>
<td>Figure 5</td>
<td>Flow diagram summarizing participant recruitment in Study 1</td>
<td>144</td>
</tr>
<tr>
<td>Figure 6</td>
<td>ROC curves for OST, QUS SI, and QUS T-score based on DXA (femoral neck) T-score ≤ -2.5 in women</td>
<td>159</td>
</tr>
<tr>
<td>Figure 7</td>
<td>ROC curves for OST, QUS SI, and QUS T-score based on DXA (lumbar spine) T-score ≤ -2.5 in women</td>
<td>160</td>
</tr>
<tr>
<td>Figure 8</td>
<td>ROC curves for OST, QUS SI, and QUS T-score based on DXA (femoral neck) T-score ≤ -2.5 in men</td>
<td>161</td>
</tr>
<tr>
<td>Figure 9</td>
<td>ROC curves for OST, QUS SI, and QUS T-score based on DXA (lumbar spine) T-score ≤ -2.5 in men</td>
<td>162</td>
</tr>
<tr>
<td>Figure 10</td>
<td>Flow diagram of study participants through the trial</td>
<td>207</td>
</tr>
</tbody>
</table>
## LIST OF APPENDICES

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A</td>
<td>Ethics Approval Letters</td>
<td>277</td>
</tr>
<tr>
<td>Appendix B</td>
<td>Recruitment Flyer and Postcard</td>
<td>281</td>
</tr>
<tr>
<td>Appendix C</td>
<td>Letter of Invitation</td>
<td>283</td>
</tr>
<tr>
<td>Appendix D</td>
<td>Eligibility Screening Form</td>
<td>285</td>
</tr>
<tr>
<td>Appendix E</td>
<td>Subject Information and Consent Form</td>
<td>287</td>
</tr>
<tr>
<td>Appendix F</td>
<td>Subject Baseline Visit Instructions</td>
<td>292</td>
</tr>
<tr>
<td>Appendix G</td>
<td>Background Health History Questionnaire</td>
<td>293</td>
</tr>
<tr>
<td>Appendix H</td>
<td>3-Day Food Record</td>
<td>302</td>
</tr>
<tr>
<td>Appendix I</td>
<td>Modified Baecke Physical Activity Questionnaire</td>
<td>308</td>
</tr>
<tr>
<td>Appendix J</td>
<td>Osteoporosis Knowledge Test</td>
<td>314</td>
</tr>
<tr>
<td>Appendix K</td>
<td>Osteoporosis Health Belief Scale</td>
<td>318</td>
</tr>
<tr>
<td>Appendix L</td>
<td>Osteoporosis Self-efficacy Scale</td>
<td>322</td>
</tr>
<tr>
<td>Appendix M</td>
<td>Follow-up Visit Instructions</td>
<td>325</td>
</tr>
<tr>
<td>Appendix N</td>
<td>Follow-up Questionnaire</td>
<td>326</td>
</tr>
<tr>
<td>Appendix O</td>
<td>Sample DXA Report</td>
<td>333</td>
</tr>
<tr>
<td>Appendix P</td>
<td>Sample Bod Pod Report</td>
<td>334</td>
</tr>
<tr>
<td>Appendix Q</td>
<td>Sample Calcaneal Quantitative Ultrasound Report</td>
<td>335</td>
</tr>
<tr>
<td>Appendix R</td>
<td>Theory-informed Osteoporosis Education Intervention Topics and Curriculum Sources</td>
<td>336</td>
</tr>
<tr>
<td>Appendix S</td>
<td>Definition of Variables in Logistic Regression Analyses</td>
<td>337</td>
</tr>
</tbody>
</table>
LIST OF ABBREVIATIONS

DXA – Dual-energy X-ray Absorptiometry

BMD – Bone Mineral Density

WHO – World Health Organization

HCP – Health Care Provider

RDA – Recommended Dietary Allowance

QUS – Quantitative Calcaneal Ultrasound

OST – Osteoporosis Self-Assessment Tool

PTH – Parathyroid hormone

HBM – Health Belief Model

RHBM – Revised Health Belief Model

HT – Hormone therapy

OHBS – Osteoporosis Health Belief Scale

OSES – Osteoporosis Self-efficacy Scale

RCT – Randomized Controlled Trial

ROC – Receiver Operating Characteristic

AUC – Area Under-the-Curve
OVERVIEW OF DISSERTATION ORGANIZATION

This dissertation is organized into the following six chapters. Chapter 1 (Introduction) provides a brief overview of the prevalence of osteoporosis and related fracture in Canada and the importance of addressing the care gap as it relates to DXA screening and health behaviour change for prevention and management of the disease.

Chapter 2 (Literature Review and Theoretical Framework) describes the epidemiology of osteoporosis and related fractures, and overall burden in Canada. The pathophysiology of osteoporosis and clinical practice guidelines for prevention and management of the disease are reviewed with particular emphasis on screening assessments, calcium and vitamin D intake, physical activity, and pharmacological treatment. This is followed by a review of the literature evaluating risk assessment screening tools and the influence of dual energy X-ray absorptiometry (DXA) screening and osteoporosis education on preventive health behaviours. Chapter 3 (Objectives) outlines the three study objectives, hypotheses and specific aims. Chapter 4 is a long paper in manuscript format and presents Study 1 results of the systematic review.

Chapter 5 and Chapter 6 are also presented as long papers in manuscript format for Study 2 and Study 3, respectively. A comprehensive description of the study designs and procedures, measurements and intervention are included. Specific analytical approaches are also described for both chapters. The final Chapter 7 (Conclusion) provides an overall summary of the research outcomes and directions for future research. Multiple tables, figures, and appendices supplement the text providing additional details related to study methodology and results.
CHAPTER 1: INTRODUCTION

This introductory chapter provides an overview of the research significance. The chapter begins by describing the general prevalence of osteoporosis and related fractures in Canada, followed by an overview of the “osteoporosis care gap” in Canada as it relates to screening and preventive health behaviours. The purpose of the research and its significance is described including the need for evaluating other osteoporosis risk assessment screening tools, and the potential role of theory-based osteoporosis education and DXA screening on health behaviour change. The chapter concludes with a statement of the practical implications of the research.

1.1 Prevalence of Osteoporosis and Related Fracture in Canada

Osteoporosis is a progressive skeletal disease characterized by low bone mineral density (BMD) with a consequent increase in bone fragility and susceptibility to fracture of the hip, spinal vertebrae, and wrist (Papaioannou, et al., 2010). An osteoporosis-related fracture (i.e., fragility fracture), particularly those of the hip and spine, is an independent predictor of subsequent fracture and associated with increased morbidity and mortality (Kanis, Johnell, et al., 2004; Papaioannou, et al., 2010). It is estimated that osteoporosis affects over 2 million Canadians of which one in four are women and one in eight are men over 50 years of age (Papaioannou, et al., 2010). Due to the rise in the aging population, the incidence of osteoporosis and related fracture is expected to increase substantially, as will the disease’s medical, economic, and social consequences. The estimated cost of treating osteoporosis and its fractures to the Canadian health care system is $2.3 billion each year and rises to $3.9 billion when taking into consideration those living in long term care (Tarride, et al., 2012). In addition to the financial burden,
osteoporosis results in reduced functional independence and quality of life (Hallberg, Bachrach-Lindstrom, Hammerby, Toss, & Ek, 2009). Therefore, preventing and managing osteoporosis and its related fractures is important for maintaining quality of life in older adults, will free up valuable health care resources, and will provide substantial cost-savings for the health care system.

1.2 The Osteoporosis Care Gap in Canada

Osteoporosis Canada, established in 1982, was the first national organization for osteoporosis in the world and focuses on raising public awareness and advocating for policy initiatives to ensure all Canadians have access to optimal osteoporosis care. Its national report on osteoporosis care called for government action to develop national, provincial, and territorial strategies to improve access to DXA screening and treatment options in effort to reduce health care expenditures for treating preventable fractures (Jiwa, et al., 2008). However, despite established clinical practice guidelines (Papaioannou, et al., 2010), in Canada less than 30% of high-risk men and women who have experienced a fragility fracture undergo screening for osteoporosis or receive treatment for osteoporosis (Giangregorio, Papaioannou, Cranney, Zytaruk, & Adachi, 2006; Papaioannou, et al., 2004). Recognizing that osteoporosis and related fractures have serious implications for both the individual affected and the overall health care system, the need for prevention and management through early detection, appropriate health behaviour change, and treatment is paramount.

Osteoporosis is a multifactorial disease making its prevention and management complex. Reducing risk of osteoporosis and related fractures requires prevention and management strategies consisting primarily of adequate calcium and vitamin D intake,
physical activity, timely diagnostic screening of BMD by DXA, and appropriate drug treatment of high-risk individuals. However, evidence suggests the majority of older adults consume inadequate amounts of calcium and vitamin D, are physically inactive, and are not receiving drug treatment, even among those who have experienced a fracture (Papaioannou, et al., 2008; Poliquin, Joseph, & Gray-Donald, 2009; Vatanparast, Dolega-Cieszkowski, & Whiting, 2009; Warburton, Katzmarzyk, Rhodes, & Shephard, 2007). Thus, there are recognized gaps not only in care between best practice and actual care delivery, but also from knowledge to practice as men and women at risk of osteoporosis and fragility fractures are not engaging in preventive health behaviours.

The current diagnostic criteria for osteoporosis, defined by the World Health Organization (WHO), are based on measurement of BMD by DXA (WHO, 1994). Canadian clinical practice guidelines outline risk factor indicators for selecting individuals over 50 years of age who should undergo DXA screening (Papaioannou, et al., 2010). Unfortunately, limited access to DXA screening sites and inadequate diagnoses are a major public health concern in Canada despite universal health care and practice guidelines for DXA screening. New risk assessment screening modalities including calcaneal quantitative ultrasound (QUS) and clinical risk factor assessment tools including the Osteoporosis Self-Assessment Tool (OST) have potential pre-screening benefits to identify individuals at risk of low BMD who should be referred for DXA screening. This would increase diagnostic screening efficiency and cost-effectiveness by reducing the number of individuals referred who are otherwise healthy.

However, the accuracy of QUS and OST in distinguishing those with osteoporosis as defined by DXA remains questionable, and comparatively, their use is less known.
Rud et al. (2009) found QUS (Achilles Lunar ultrasound, GE Medical) was more accurate than OST regardless of BMD site in white postmenopausal women; however, these studies were reported as abstracts. While official positions on QUS in the management of osteoporosis recommend it not be used to diagnose osteoporosis, developing pre-defined, device-specific diagnostic cut-offs of specific populations by sex, age, and ethnicity based on QUS results has been suggested (Krieg, et al., 2008). Cut-offs proposed in research literature for both QUS and OST are limited for men and women; thus there is a need to determine not only the accuracy of these risk assessment screening tools, but to also define optimal cut-offs to identify osteoporosis risk in older men and women.

When combined with timely follow-up, DXA screening results play an important role informing not only health care providers (HCPs) clinical decisions and recommendations for prevention and management of the disease, but also patients’ decisions to modify health behaviours (Brennan, Wactawski-Wende, Crespo, & Dmochowski, 2004; McLeod, McCann, Horvath, & Wactawski-Wende, 2007; Papaioannou, et al., 2008). Therefore, if individuals are being screened but unaware of their results, they may be less likely to engage in preventive health behaviours. Research literature evaluating the influence of DXA screening results on older men and women’s decisions to change health behaviours and/or initiate treatment is limited (Brennan, et al., 2004; Doheny, Sedlak, Hall, & Estok, 2010; McLeod, et al., 2007; Rohr, Clements, & Sarkar, 2006). No studies have assessed change in vitamin D intake and only one study has evaluated older men. In addition, assessment of health behaviours has been largely based on self-report with little detail of the measurement methodology and few studies
have evaluated confounding factors associated with behaviour change. It is worthwhile to assess calcium and vitamin D intake, physical activity, and drug treatment initiation to understand the full influence of DXA screening on change in these health behaviours. Further understanding of the factors that influence decisions to initiate change may also be useful in developing health promotion strategies to reduce risk.

Screening may be the first step in improving the osteoporosis care gap; however, there is also a traditional lack of knowledge and awareness about the disease among older men and women. Combined with DXA screening, increased knowledge and awareness about osteoporosis can help older adults make informed decisions about health behaviours for the prevention and management of the disease. Thus, there is a crucial need to address primary prevention of osteoporosis as it relates to health promotion of modifiable health behaviours in this population. The Revised Health Belief Model (RHBM) is one of the most widely used theoretical frameworks in health behaviour and suggests that an individual’s health beliefs and self-efficacy are associated with health behaviours (I. Rosenstock, Strecher, & Becker, 1988). Osteoporosis education intervention studies using the RHBM as a guiding framework are limited and vary in study population and design, method of education intervention, and length of follow-up (Babatunde, Himburg, Newman, Campa, & Dixon, 2011; Sedlak, Doheny, & Jones, 2000; Tussing & Chapman-Novakofski, 2005). Additionally, research assessing the influence of theory-based osteoporosis education combined with DXA screening on health behaviour change in older men and women is lacking. Therefore, it is necessary to determine whether DXA screening alone is adequate to promote health behaviour change,
1.3 Research Objectives

The objectives of this study were three-fold and emphasized primary and secondary prevention of osteoporosis in effort to reduce the care gap. The first objective of the study (Study 1) was to conduct a systematic review to identify common validated clinical risk factor assessment tools in predicting low BMD in postmenopausal women and determine which tool has the best discriminative performance. Results of the systematic review informed the objective of Study 2. The second objective of the study (Study 2) was to evaluate the accuracy of QUS and OST in identifying men and women over 50 years of age with osteoporosis as defined by DXA. A further aim of this study was to identify optimal cut-offs for both pre-screening tools for determining osteoporosis risk in this population. The third objective of the study (Study 3) was to determine the influence of DXA screening results combined with theory-based osteoporosis education versus usual care (DXA screening alone) on change in older men and women’s health behaviours, specifically calcium and vitamin D intake, physical activity, and drug treatment initiation.

1.4 Research Significance to the Osteoporosis Care Gap

Findings from the three studies have practical significance by providing older adults, HCPs, and health care institutions insight and practical solutions regarding useful strategies for osteoporosis education, prevention, detection and treatment. Results of this research will allow us to better understand the implications of DXA screening results and theory-informed osteoporosis education, an understanding that will favourably influence
both management and education strategies to reduce existing knowledge and care gaps in Canada. These research findings will contribute to advancing the provincial health goals for Saskatchewan. With regard to improved access to diagnostic screening, while QUS cannot replace DXA screening, it may be a useful pre-screening device in rural areas where access to DXA screening is limited. Additionally, a better understanding of the factors associated with health behaviour change among older men and women may help inform health promotion programs targeted at improving calcium and vitamin D intake, physical activity, and treatment initiation for prevention and management of osteoporosis, and ultimately reduce fracture risk.
CHAPTER 2: LITERATURE REVIEW AND THEORETICAL FRAMEWORK

This chapter begins with a summary of the epidemiology of osteoporosis and related fracture, and its overall burden in Canada. The pathophysiology of osteoporosis and the Canadian clinical practice guidelines for prevention and management of the disease are reviewed, with particular emphasis on calcium and vitamin D intake, weight-bearing physical activity, pharmacological treatment, and screening assessments. This is followed by a review of the literature as it relates to Study 1 and Study 2, summarizing risk assessment screening devices and tools including DXA, QUS, and OST and the discriminatory ability of QUS and OST compared to DXA, the reference standard. Next, research assessing the influence of DXA screening on health behaviours is summarized as it pertains to Study 3. The chapter concludes with a summary of the theoretical framework chosen to guide the education intervention for Study 3, followed by a review of the literature on the influence of osteoporosis education combined with DXA screening on health behaviours.

2.1 Epidemiology of Osteoporosis and Related Fracture

Osteoporosis is a chronic disease that has escalated to what is considered a major public health concern in developed countries. Defined as a chronic, asymptomatic skeletal disease, osteoporosis is characterized by decreased bone mass with a consequent increase in bone fragility and risk of fracture, particularly of the hip, spine, and wrist. Literally meaning “porous bones”, osteoporosis is by far the most common bone disease.

The prevalence of osteoporosis, as determined by BMD measurements by DXA, increases markedly with age. Although once thought to be an inevitable consequence of aging in women, extensive research and recognition in the past two decades show it is a
disease affecting millions of older men and women. In Canada, it is estimated that over 2 million Canadians have osteoporosis, of which one in four are women and one in eight are men over 50 years of age. Additionally, approximately 46% of postmenopausal women and 40% of men over 50 years of age are estimated to have osteopenia and are therefore, at increased risk of developing osteoporosis (Tenenhouse, et al., 2000).

Statistics Canada (2012) estimates that in 2011, 5 million Canadians were 65 years of age or older. This number is expected to double in the next 25 years reaching 10.4 million older adults by 2036 and by 2051, about one in four Canadians is expected to be over 65 years. With the prevalence of osteoporosis increasing with age and the rapidly aging population, it is projected that Canadians developing osteoporosis and experiencing related fractures will rise considerably (Papadimitropoulos, Coyte, Josse, & Greenwood, 1997).

2.1.1 Clinical Consequences

The clinical significance of osteoporosis lies in the fractures that arise when bones become severely weakened by the disease. Osteoporotic fractures may occur not only from a fall from standing height, but also from simple movements such as normal lifting and bending. It is estimated that at least one in three women and one in five men will experience an osteoporotic fracture during their remaining lifetime (Cummings & Melton, 2002). Of those over 50 years of age who experience a fracture, greater than 80% are osteoporosis related, yet less than 30% of fracture patients are diagnosed and treated for osteoporosis in Canada (Giangregorio, et al., 2006; Papaioannou, et al., 2004; Papaioannou, et al., 2008). These startling statistics highlight the paramount need for risk reduction and early detection of osteoporosis and related fracture.
The impact of osteoporotic fractures, particularly of the hip and spine, is significant as they are often associated with considerable morbidity and mortality (Ioannidis, et al., 2009). Osteoporotic fractures require many medical resources including hospitalization, long term care, home health care, and physical therapy; however, there remains inadequate diagnosis and treatment even after fracture occurs. In Canada, approximately 30,000 hip fractures occur annually, of which it is estimated that 80% are osteoporosis related (Leslie, O'Donnell, et al., 2009). Hip fractures are among the most devastating, with 28% of women and 37% of men facing death within the following year (Jiang, et al., 2005). Increased mortality rates after hip fracture are partly due to co-morbidity as hip fracture patients often suffer from additional diseases compared to the general population (Kanis, et al., 2003). It is estimated that only 44% of individuals discharged from hospital after hip fracture return home; of the remaining, 10% go to another hospital, 27% go to rehabilitation care, 17% go to long-term care facilities, and less than half regain their pre-fracture functioning with regard to activities of daily living (Melton, 2003). Due to the rise in the aging population, by the year 2041, the number of hip fractures in Canada is expected to increase to 88,124 with a parallel increase in associated hospital days from 465,000 to 1.8 million if improvements in osteoporosis care are not addressed (Papadimitropoulos, et al., 1997).

Although osteoporosis is less prevalent in men than women, it is estimated that one third of all hip fractures occur in men and vertebral deformities, which typically represent vertebral fractures, are seen in 21.5% of men and 23.5% of women over 50 years of age (Khan, et al., 2007). Vertebral fractures are associated with increased incidence of morbidity, mortality, and are a major risk factor for future fracture,
particularly hip fracture (Ismail, et al., 2001; Klotzbuecher, Ross, Landsman, Abbott, & Berger, 2000). In the Fracture Intervention Trial, relatively healthy women \((n = 6,459)\) aged 55 to 81 years were followed for 3.8 years to assess the risk of mortality after fracture. Results showed clinical vertebral fractures and hip fractures were associated with a substantial increase in mortality (Cauley, Thompson, Ensrud, Scott, & Black, 2000). Unfortunately, only approximately 30% of vertebral fractures are diagnosed, as often individuals do not seek medical attention to report back pain, or a physician does not suspect a fracture and order a radiograph (Papaioannou, et al., 2002).

2.1.2 Economic Burden

The economic consequences of osteoporosis and related morbidity and mortality due to osteoporotic fractures are staggering. The estimated annual cost of treating osteoporosis and related fractures to the Canadian health care system is $2.3 billion each year, with the majority attributed to hip fracture. These costs include acute care costs, outpatient care, prescription drugs, and indirect costs. These costs rise to $3.9 billion when taking into consideration those living in long term care (Tarride, et al., 2012). A longitudinal cohort study evaluated the individual one-year societal cost of hip fracture in Canadians over 50 years of age who were admitted to an acute care facility (Wiktorowicz, Goeree, Papaioannou, Adachi, & Papadimitropoulos, 2001). Results showed the average individual one-year cost including institutional services, initial hospitalization, re-hospitalization, rehabilitation, long term care, home care and informal care was $21,285 after hospitalization, and $44,156 if the patient was institutionalized. Notably, this study was based on data from only four hospitals in a single region in Ontario and may not be representative of the country as a whole.
Worldwide, the economic burden of osteoporosis is similar to that seen in Canada. Osteoporosis related fractures in the United States are responsible for an estimated $19 billion in costs, with men accounting for over 25% of the burden (National Osteoporosis Foundation, 2012). By 2025, researchers predict that osteoporosis and its fractures and their costs will grow by more than 48% resulting in $25.3 billion in health care costs. Of increasing concern is the fast growth of the disease burden among the non-white population. These values for both Canada and the United States are a considerable underestimation of the true costs of osteoporosis, as treatment costs for individuals without history of fracture and indirect costs of lost wages, productivity, and other human costs are not taken into account.

2.2 Classification and Pathophysiology of Osteoporosis

While prevention and management of osteoporosis related fractures is an important and costly issue within the health care system, research addressing the physiological development and maintenance of bone is also important to understanding the pathophysiology of osteoporosis in order to prevent and treat the disease. This section will discuss the structure and histology of bone tissue as well as the bone remodelling process. Research literature discussing the clinical usefulness of biochemical markers of bone turnover and classification of osteoporosis will also be addressed.

2.2.1 Bone Architecture

Bone is a very complex structure essential for providing mobility, support, and protection for the human body, as well as a reservoir for storing essential minerals. There are two main components of bone strength: BMD (mineral content in grams per area) and bone quality (bone architecture, bone turnover, damage accrual to the bone, matrix
properties, and mineralization). BMD is the most commonly expressed measure of overall bone strength, estimated to account for approximately 70% of bone strength. Therefore, BMD is measured for diagnosis of osteoporosis and to provide information on fracture risk.

Healthy bone is composed of two types of structural tissue: cortical and trabecular tissue. Cortical bone is essential for providing strength and sites for attachment of tendons and muscles. It makes up approximately 80% of the skeleton, forming the dense outer shell which protects and encases the inner trabecular bone. Cortical bone has a slow turnover rate and a high resistance to bending and torsion, thus its thickness and porosity are important components of bone strength (Felsenberg & Boonen, 2005). The remaining 20% of the skeleton, trabecular bone is composed of a fine, sponge-like lattice and is less dense with a higher turnover rate than cortical bone, thus exhibiting a major metabolic function. Trabecular bone is the primary site for mineral exchange in order to maintain skeletal strength and quality, whereas cortical bone participates in metabolic responses typically when under prolonged mineral deficiency or in late adulthood (Griffith & Genant, 2008). The orientation, thickness, and spacing of the trabeculae, as well as the extent to which the trabeculae are interconnected are important components of bone strength (Felsenberg & Boonen, 2005). Trabecular bone is prominent in the spinal vertebrae and ends of the long bones, such as the femur, making fractures common at these sites when bone is weakened (Einhom, 1992; Griffith & Genant, 2008; Kontulainen, Sievanen, Kannus, Pasanen, & Vuori, 2003). The relative contribution of cortical versus trabecular bone in bone strength at common fracture sites has not been established. Osteoporosis is a result of cortical thinning and trabecular bone loss.
especially in areas where trabecular bone is prominent. The structure of bone tissue is well-documented in the research literature; however, the bone remodelling process and its molecular mechanism continues to evolve. The following section will discuss current research literature in this area.

2.2.2 Bone Remodelling

During childhood and adolescence bones are developed by a process called modeling which allows individual bones to grow in size, thickness, and density. This process involves the formation of new bone on the periosteal surface (dominant process) and corresponding resorption of old bone on the endosteal surface within the same bone (E. Seeman, 2003). By approximately the early 20’s, individuals reach peak bone mass, the maximum amount of bone density achieved (Heaney, et al., 2000). Peak bone mass is largely determined by genetics; however studies have shown that calcium intake, weight-bearing physical activity, and hormonal status, in particular early age of onset puberty, are also influential modifiable factors (Heaney, et al., 2000).

In healthy adult bone, normal bone turnover is an ongoing process of bone mineral formation and resorption, also known as remodelling (Manolagas, 2000). This process replaces approximately 10% of the skeletal tissue per year, thus most of the adult skeleton is replaced about every 10 years (Tortora & Derrickson, 2009). Bone remodelling is necessary for repairing skeletal damage or deformities, increasing bone strength, maintaining mineralization, and preventing accrual of old bone, which can lose its strength and become brittle (Raisz, 1999). Orderly bone remodelling depends on a precise balance between formation and resorption, and is carried out through the
collaborative action of specialized cells called osteoblasts and osteoclasts, collectively known as a basic multicellular unit (BMU).

The cells that mediate bone formation and mineralize bone are called osteoblasts. They develop from mesenchymal stem cells and are found in clusters along the bone surface and synthesize collagen of the bone matrix, which hardens by mineral deposition. Mechanical loading and fractures generate increased numbers of osteoblasts and osteoblastic activity, which reinforces or rebuilds the bone. Osteoclasts are multinucleated cells that mediate bone resorption. They develop from hematopoietic stem cells, the same bone marrow stem cells that give rise to blood cells. Osteoclasts often reside in cavities called Howship’s lacunae that they carve into the surface of the bone matrix, and resorb bone by acidification and proteolytic digestion (Manolagas, 2000). When the activity of the osteoblasts and osteoclasts is coupled, bone mass is stable; however, an imbalance in the activities of these two cell types can result in loss of BMD (E. Seeman, 2003). Between 30 and 35 years of age, bone resorption naturally begins to exceed formation and more bone mineral content is resorbed than is formed, resulting in a gradual decline in BMD, which is further exacerbated by risk factors such as physical inactivity and inadequate calcium and vitamin D intake. At the time women reach menopause, bone loss accelerates substantially by approximately 2% to 5% per year (Hannan, et al., 2000). This rapid rate of bone loss continues for up to five to 10 years at which point it returns to premenopausal levels (Black, 1995). Bone density continues to decrease in both elderly men and women at a rate of 0.5% to 1.0% per year (Cummings, 1993). In addition to adult bone loss, osteoporosis may also be due to sub-optimal bone growth during childhood and adolescence.
Remodelling follows a specific sequence of activation first, then resorption, followed by reversal, and finally formation (see Figure 1). Activation begins when lining cells (osteoblasts that lay on the bone surface to add strength to the bone matrix) retract, exposing the matrix for resorption by osteoclasts. The resorption phase begins with the migration of osteoclast precursors (hematopoietc cells) to the exposed bone surface where they attach to the bone as multinucleated osteoclasts (Hadjidakis & Androulakis, 2006). Osteoclasts resorb bone, which leads to the development of Howships’s lacunae (Manolagas, 2000).

The activation and resorption phases are followed by a brief reversal phase during which the resorbed surface is prepped for bone formation (Everts, et al., 2002). These three phases occur rapidly, lasting approximately two to three weeks in adults. During the reversal phase, mononuclear cells appear in a thin layer on the bone surface in preparation of new osteoblasts to begin bone formation. The final phase, bone formation, takes much longer, lasting approximately three to four months (Hadjidakis & Androulakis, 2006). Bone formation occurs when osteoblasts begin to replace bone in resorbed cavities until all resorbed bone is replaced by new bone. Osteoblasts lay down successive, orderly layers of collagen matrix, which is then mineralized with a lag of approximately 10 days behind the advancing matrix (Hauge, Qvesel, Eriksen, Mosekilde, & Melsen, 2001). When bone formation commences, remaining osteoblasts become quiescent on the bone surface and turn into lining cells until a new remodelling cycle begins. Some osteoblasts that remain embedded in the hardened matrix form osteocytes (mature osteoblasts that help maintain homeostasis of the bone and monitor strain as a result of mechanical loading).
2.2.3 Biochemical Markers of Bone Turnover

The bone turnover rate is a function of the bone remodeling process. Bone remodeling is measured using biochemical markers of bone turnover in the serum or urine (Eastell & Hannon, 2008). Biochemical markers provide clinically useful evidence of the normal and pathologic processes reflecting bone cell activity. They are divided into two categories: markers of bone resorption and markers of formation. The principal biochemical markers of bone resorption reflect osteoclast activity and are degradation products of type 1 collagen which is the most abundant protein of bone matrix (e.g. N-terminal and C-terminal crosslinking telopeptides, and hydroxyproline) (Eastell & Hannon, 2008; Szule & Delmas, 2008). Biochemical markers of bone formation reflect osteoblast activity and include byproducts of collagen synthesis, osteocalcin, and osteoblastic enzymes (e.g. total alkaline phosphatase and bone alkaline phosphatase) (Eastell & Hannon, 2008; Szule & Delmas, 2008). These biochemical markers of bone turnover have been shown to predict bone loss, as well as fracture risk independently of BMD in postmenopausal and elderly women (Garnero, Sornay-Rendu, Claustrat, & Delmas, 2000; Gerdhem, et al., 2004). Specifically, markers of bone resorption have been shown to be significantly elevated in postmenopausal women with osteoporosis compared to postmenopausal women with normal BMD. However, markers of bone formation are far less elevated suggesting the imbalance of bone resorption and formation that occurs with osteoporosis. Very few studies assess markers of bone turnover in men and available data are variable (Szule, Kaufman, & Delmas, 2007). The clinical usefulness of bone turnover markers as non-invasive, cost-effective adjuncts to screening for bone loss and their response to osteoporosis drug therapy requires further research.
2.2.4 Classification of Osteoporosis

Osteoporosis can be further classified as either primary or secondary. Primary osteoporosis, the most common form, is not related to other diseases or conditions, contrary to secondary osteoporosis, and can be classified according to age groups. Primary osteoporosis is frequently associated with postmenopausal women (often called type 1 osteoporosis) due to a decrease in estrogen levels and thus increased osteoclast activity and accelerated bone loss. Also, women in general reach a lower peak bone mass than males and have a longer average life expectancy, thus osteoporosis is more common among postmenopausal women. Age-related osteoporosis (often called type 2 osteoporosis) describes the disease in the elderly and is evident in men and women. Secondary osteoporosis occurs when an identifiable cause other than age or menopause is present. It is diagnosed when osteoporosis is related to another illness such as hyperthyroidism or rheumatoid arthritis, or the use of medications such as glucocorticoid steroids or chronic heparin therapy.

2.3 Prevention and Management of Osteoporosis

2.3.1 Risk Factors for Low Bone Mineral Density

Osteoporosis is referred to as a “silent” disease as bone loss often occurs without symptoms until a related fracture occurs. Much of the burden of osteoporosis may be avoided if preventive measures are followed as early as possible to ensure maintenance of BMD thus preventing fracture. In order to strive for optimal prevention and management of the disease, it is important that individuals and their HCPs are aware of osteoporosis risk factors. Establishing individual risks based on presence of osteoporosis risk factors will aid HCPs in identifying who should undergo DXA screening. This is an important
basis from which individuals can make accurate decisions regarding health behaviour changes for prevention, and, with advice from a HCP, consider appropriate treatment to help maintain optimal BMD and decrease the risk of osteoporotic fracture.

Based on a recently revised protocol for diagnosis and management of osteoporosis in Canada, men and women over 50 years of age should be routinely screened for osteoporosis risk factors to identify those at high risk (Papaioannou, et al., 2010). These Canadian clinical practice guidelines outline risk factor indicators for selecting individuals who should undergo DXA screening – an important component of the practice guidelines, which use an integrated approach for the management and treatment of osteoporosis and fractures (Papaioannou, et al., 2010). The practice guidelines identify the following risk factors for low BMD (Table 1) and indicate that an individual having one or more of the following risk factors should subsequently undergo BMD screening by DXA (Papaioannou, et al., 2010).
Table 1.

*Risk Factor Indicators for Measuring BMD by DXA*

<table>
<thead>
<tr>
<th>Older Adults (age ≥ 50 years)</th>
<th>Younger Adults (age &lt; 50 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 65 years (men and women)</td>
<td>Fragility fracture</td>
</tr>
<tr>
<td>Clinical risk factors for fracture (menopausal women, men age 50-64 years)</td>
<td>Hypogonadism or premature menopause (age &lt; 45 years)</td>
</tr>
<tr>
<td>Fragility fracture after age 40 years</td>
<td>Use of other high-risk medications&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Prolonged use of glucocorticoids&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Prolonged use of glucocorticoids&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Use of other high-risk medications&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Malabsorption syndrome</td>
</tr>
<tr>
<td>Parental hip fracture</td>
<td>Primary hyperparathyroidism</td>
</tr>
<tr>
<td>Vertebral fracture or osteopenia identified on radiography</td>
<td>Other disorders strongly associated with rapid bone loss and/or fracture</td>
</tr>
<tr>
<td>Current smoking</td>
<td></td>
</tr>
<tr>
<td>High alcohol intake (three or more drinks/day)</td>
<td></td>
</tr>
<tr>
<td>Low body weight (&lt; 60 kg) or major weight loss (&gt; 10% of body weight at age 25 years)</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td></td>
</tr>
<tr>
<td>Other disorders strongly associated with osteoporosis (e.g. celiac disease, chronic liver disease, etc.)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>At least three months cumulative therapy in the previous year. <sup>b</sup>For example, aromatase inhibitors or androgen deprivation therapy.
Several of the major risk factors for osteoporosis are non-modifiable (e.g., age and parental history) and largely determine whether an individual is at increased risk. In women, the rate of bone resorption increases at menopause due to the reduction of estrogen production. Although the mechanism is not completely understood, estrogen deficiency results in osteoclastogenesis, thereby increasing the number, activity, and lifespan of osteoclasts which produce more, as well as deeper resorption cavities on the bone surface, while the lifespan of osteoblasts decreases. With regard to parental history as a non-modifiable risk factor, a meta-analysis showed parental history of fracture, particularly hip fracture was significantly associated with an increased risk of all osteoporotic fracture ($RR = 1.54$, 95% CI [1.25, 1.88]) and of hip fracture ($RR = 2.27$, 95% CI [1.47, 3.49]) in men and women combined (Kanis, Johansson, et al., 2004).

Gender and ethnicity, although not listed as risk factor indicators for BMD measurement, are recognized by the International Osteoporosis Foundation (IOF) as non-modifiable risk factors for osteoporosis (International Osteoporosis Foundation, 2013). Women, particularly post-menopausal women, are more susceptible to bone loss than men, and research shows Caucasian and Asian populations are at greater risk of the disease (Lau, Lynn, Woo, & Melton, 2003).

Modifiable risk factors listed in Table 1, including smoking and excessive alcohol intake, also play a significant role in the rate of bone loss associated with aging. A meta-analysis of 59,232 men and women (74% female) from 10 prospective cohorts across several countries found smoking history was associated with a significantly increased risk of osteoporotic fracture, ($RR = 1.29$, 95% CI [1.13, 1.28]) and hip fracture ($RR = 1.84$, 95% CI [1.52, 2.22]) compared with individuals with no smoking history (Kanis, Johnell,
et al., 2005). While moderate consumption of alcohol may be beneficial to bone in older men and postmenopausal women, a meta-analysis showed excessive intakes (consistently more than three drinks a day) of alcohol significantly increase risk of osteoporotic fracture ($RR = 1.38$, 95% CI [1.16, 1.65]) or hip fracture ($RR = 1.68$, 95% CI [1.19, 2.36]) in older men and women (Kanis, Johansson, et al., 2005).

It is important to note from a population health perspective it is now recognized that many other factors, beyond the behavioural and genetic determinants discussed, have a powerful effect on bone health, including socioeconomic status and education. These social disparities influence osteoporosis and related fracture incidence, prevention and management largely due to inequities in access to DXA screening, treatment, and health promotion education. Research studies in the Canadian population have shown a relationship between access to DXA screening services and geographic area of residence, particularly rural, remote and northern areas (Finkelstein, 2002; Jaglal, et al., 2000; Vanasse, et al., 2005). Low socioeconomic status is also a barrier to DXA screening despite universal health care coverage for DXA screening (Hurley & Grignon, 2006; van Doorslaer, Masseria, & Koolman, 2006). Health behaviour changes are also largely related to social determinants (Glouberman, 2001). Low socioeconomic status, sub-standard housing, and low levels of education largely influence the adoption of unhealthy behaviours such as poor dietary choices, physical inactivity, and tobacco use, which are risk factors for osteoporosis (Raphael, 2008). With regard to education, it may be that individuals who are more educated may be more informed and knowledgeable about osteoporosis and the importance of diagnostic screening and preventive health behaviours for prevention and management (Dunlop, Coyte, & McIsaac, 2000; Hurley & Grignon,
2006). Therefore, it is important to not only educate individuals about the risk factors for osteoporosis, but to address the entire range of factors, including social disparities, that influence health in order to improve the osteoporosis care gap (Farahmand et al., 2000).

It is clear osteoporosis is a multifactorial disease making its prevention and management complex. The goals for management of osteoporosis and related fracture are to establish individual risk based on presence of risk factors for the disease and DXA screening results, and to make appropriate decisions regarding prevention or treatment. Prevention and management strategies consisting primarily of adequate intake of calcium and vitamin D, physical activity incorporating weight-bearing exercise, strength, and balance training, and appropriate drug treatment are important modifiable health behaviours that should be encouraged for bone health in all men and women over 50 years of age (Papaioannou, et al., 2010). Although these modifiable factors are essential for osteoporosis prevention and management, there is a well-documented care gap from knowledge to practice.

### 2.3.2 Calcium and Vitamin D Intake

Adequate calcium and vitamin D intake play a fundamental role in the development of peak bone mass and the prevention of age-related bone loss. While calcium and vitamin D should not be used solely for prevention and treatment of osteoporosis, they have been shown in both dietary and supplement form to be essential adjuncts to prevent and manage osteoporosis.

Calcium is the most abundant mineral in the body. The adult human body contains approximately 1,000 to 1,500 g of calcium (depending on gender, race, and body size), of which 99% is stored in the bones in the form of hydroxyapatite. The remaining
1% of calcium in the body circulates in serum and serves as a reserve from which free calcium can be obtained by bone if needed. In bone, calcium plays an essential structural role and regulates extracellular calcium concentration. Vitamin D (calcitriol or 1,25(OH)_{2}D_{3}), synthesized in the epidermis under the presence of UVB radiation from the sunlight or derived from the diet, is required for optimal absorption of calcium in the small intestine.

The natural aging process results in obligatory calcium losses that can be offset by sufficient calcium and vitamin D intake. These losses include decreased intestinal absorption of calcium, decreased capacity of the skin to synthesize vitamin D, and decreased efficiency of the kidneys to retain calcium, leading to increased calcium loss in the urine (Pattanaungkul, Riggs, & Yergey, 2000). Also, when women reach menopause, bone resorption rate rises due to a fall in estrogen production. Unfortunately, older adults tend to be at greater risk of calcium and vitamin D deficiency due to decreased dietary intake, usually as a result of decreased overall dietary energy intake (e.g., poor appetite, social and economic factors) and infrequent exposure to sunlight (e.g., elderly who are housebound, or institutionalized, or have reduced mobility). Calcium and vitamin D deficiency leads to reduced calcium absorption, increased PTH production, and ultimately increased risk of osteoporosis and related fracture (Figure 2). Lowered PTH levels remove the stimulus for bone resorption and have long been considered an important mechanism by which vitamin D improves BMD (Dawson-Hughes & Bischoff-Ferrari, 2007)
Figure 2. Flowchart of mechanisms leading to low bone mineral density and fracture by calcium and vitamin D deficiency.
It is well established that optimized calcium and vitamin D intake have a protective effect on bone density and play a role in prevention of osteoporosis and related fracture (Daly, Brown, Bass, Kukuljan, & Nowson, 2006; Tang, Eslick, Nowson, Smith, & Bensoussan, 2007). One of the earliest studies demonstrating this protective effect was carried out by Dawson-Hughes et al. (1997). They studied the three-year effect of calcium and vitamin D supplementation (500 mg and 700 IU respectively) on BMD and incidence of non-vertebral fractures in 176 men and 213 women 65 years of age and older. Results showed the difference between calcium and vitamin D supplementation and placebo groups was significant at the spine ($p = 0.04$) and femoral neck ($p = 0.02$) after one year, and significant for the total body BMD ($p < 0.01$) in the second and third years. Of the 37 participants who suffered fracture, 26 were in the placebo group ($p = 0.02$).

A randomized controlled trial (RCT) of 167 men over 50 years of age found that consuming 400 ml/day of reduced fat milk containing 1,000 mg of calcium and 800 IU of vitamin D for two years was effective for increasing serum $25(OH)D_3$ and decreasing PTH concentrations relative to the control group after the first year (31% and 19%, $p < 0.01$, respectively) and these differences remained after two years. Supplementation also reduced the rate of bone loss at the femoral neck, total hip, and ultradistal radius with mean percent change in BMD of 0.9 to 1.6% less in the supplemented group compared with the control group (Daly, et al., 2006).

The largest calcium and vitamin D supplementation study carried out to date by the Women’s Health Initiative (WHI) found that healthy postmenopausal women ($N = 36,282$) taking calcium (1,000 mg) and vitamin $D_3$ (400 IU) supplements daily for an average of seven years resulted in a small but statistically significant increase (1.06%, $p <
in femoral neck BMD for those taking their supplements consistently compared to those taking a placebo (Jackson, et al., 2006). While this was a significant increase, unlike the previous studies mentioned, the average calcium intake at baseline was 1,000 mg/day, close to the current national recommendation of 1,200 mg/day. The majority of individuals in the placebo group (64%) had a daily calcium intake from diet and supplements of at least 800 mg at baseline, and 42% had a daily vitamin D intake of at least 400 IU. There is general consensus that the greatest effects of calcium and vitamin D supplementation on bone health occur in individuals with low BMD or osteoporosis in the presence of calcium or vitamin D deficiencies (Papadimitropoulos, et al., 2002).

There were other limitations to the WHI study. More than half of the participants were receiving hormone therapy (HT) at baseline, which has been shown to significantly reduce the risk of osteoporosis and related fracture. However, widespread use of HT has since declined based on findings from the WHI RCT that showed risks associated with HT use; therefore generalizability of the results is limited (Cauley, et al., 2003). Also, only 400 IU of vitamin D was supplemented daily, which may not have been sufficient to effect a change in BMD. It can be concluded that while calcium and vitamin D supplementation has a protective effect, engaging in this health behaviour alone is not enough to ensure optimal bone health and should be combined with other preventive measures such as physical activity and drug treatment.

Recently, several meta-analyses have provided insight to the beneficial effects of calcium, vitamin D, or their combination, on fracture risk. The most recent meta-analysis conducted by Tang, Eslick, Nowson, Smith, and Bensoussan (2007) included 17 randomized trials with a total of 52,625 men and women over 50 years of age to assess
the effects of calcium and calcium in combination with vitamin D on total fracture at all sites. Treatment was associated with a 12% risk reduction in fractures at all sites (RR = 0.88, 95% CI [0.83, 0.95], p < 0.001). Of the 24 trials reporting BMD only, calcium and calcium in combination with vitamin D were associated with a reduced bone loss of 0.54% (95% CI [0.35, 0.73], p < 0.001) at the hip and 1.19% (95% CI [0.76, 1.61], p < 0.001) at the spine. The addition of vitamin D to calcium did not significantly change treatment effect. The authors concluded that outcomes may have been influenced by the inclusion of trials lacking a control group, and trials themselves were heterogeneous with regard to methods of fracture reporting.

Another recent meta-analysis included nine RCTs of 53,260 postmenopausal women in total. Results showed calcium and vitamin D supplementation significantly reduced the risk of hip fracture by 28%, and the risk of non-vertebral fracture by 23% compared to supplementation with vitamin D alone, which was not found to significantly reduce fracture (Boonen, et al., 2007). Overall, based on the results of the studies discussed, it is evident that given widespread access to calcium and vitamin D supplements, as well as their low cost, supplementation compared to the high economic burden of osteoporosis and related fracture is justified.

Despite the abundant evidence supporting calcium and vitamin D intake for osteoporosis prevention, there has been question about the optimal combination and amount of calcium and vitamin D older adults should consume. In the studies previously discussed, subjects were supplemented with varying amounts of calcium and vitamin D. In particular, the acceptable threshold for calcium intake is unclear and recommendations vary between countries from 1,200 to 1,500 mg/day. The current recommended dietary
allowance (RDA) of calcium for healthy men and women over 50 years of age is 1,200 mg/day. The WHO recommends postmenopausal women and men 65 years of age and older consume 1,300 mg/day for optimal bone health; however, Osteoporosis Canada and practice guidelines recommend men and women over 50 years of age consume 1,200 mg/day through diet and supplements (Papaioannou, et al., 2010).

Vitamin D supplementation must be sufficient enough to ensure that serum 25(OH)D$_3$ values reach threshold levels; otherwise, it will not provide benefits in the aided absorption of calcium. However, there is no consensus on the breakpoint where deficiency begins. Published estimates suggest serum 25(OH)D$_3$ below which serum PTH concentrations begin to rise range between 30 and 100 nmol/l (Dawson-Hughes, et al., 2005). A recent quasi-consensus of vitamin D experts (five out of six), including a Canadian representative, determined a threshold of 75 nmol/l of serum 25(OH)D concentration in older individuals was essential for optimal bone health and lowered risk of fracture (Dawson-Hughes, et al., 2005). The RDA for men and women ages 51 to 70 years and over 70 years of age is respectively, 15 μg (equivalent to 600 IU) and 20 μg (equivalent to 800 IU). However, studies have shown that 400 IU of vitamin D per day was not sufficient to have an effect on bone loss and fracture rate (Bischoff-Ferrari, et al., 2005). For men and women over 50 years of age, Osteoporosis Canada and practice guidelines recommend 800 to 2,000 IU of supplemental vitamin D per day for osteoporosis prevention and management (D. A. Hanley, Cranney, Jones, Whiting, & Leslie, 2010; Papaioannou, et al., 2010). This is consistent with evidence that shows 800 IU (20 μg) of vitamin D$_3$ daily prevents osteoporosis and related fractures in adults older than 65 years (D. A. Hanley, et al., 2010; Vieth, 2005).
Despite the calcium and vitamin D recommendations put forth by Osteoporosis Canada, the majority of older adults have intakes below recommended amounts. Nutrient intake data from adult Canadians in the 1990’s were estimated by combining published data from nine provincial nutrition surveys. Results showed average calcium intake from food for men and women ages 50 to 64 years and 65 to 74 years was respectively, 808 mg and 676 mg, and 765 mg and 638 mg (Dolega-Cieszkowski, Bobyn, & Whiting, 2006). Vatanparast, Dolega-Cieszkowski, and Whiting (2009) also evaluated calcium intake from food from 1970 to 2004 from nine provincial nutrition surveys and the Canadian Community Health Survey (CCHS) and found mean calcium intake was below the RDA despite the onset of calcium fortification in the 1990’s. In particular, men and women 51 years of age and older had intakes below the RDA in the province of Saskatchewan. Results from the longitudinal Canadian Multicentre Osteoporosis Study (CaMos) study, showed dietary and supplement calcium intake for women ages 51 to 70 years \( (n = 3,508) \) and over 70 years \( (n = 1,963) \) was 1,063(631) mg and 1,035(598) mg, respectively. For men ages 51 to 70 \( (n = 1,380) \) and over 70 years \( (n = 750) \), calcium intake was 1,035(598) mg and 884(557) mg respectively (Poliquin, et al., 2009).

In the United States, national dietary survey data have also consistently shown that calcium intakes, especially among the elderly, are well below the recommended 1,200 mg per day. The USDA’s Continuing Survey of Food Intakes by Individuals (CSFII) 1994-96 showed only 14.6% of men and 5% of women ages 50 to 59, 13.0% and 3.6% of men and women aged 60 to 69 respectively, and 12.6% and 3.6% of men and women ages 70 and older respectively consumed 100% of the calcium recommendation (G. D. Miller & Anderson, 1999). Also, data from the third National Health and Nutrition
Examination Survey (NHANES III) conducted from 1988 to 1994 combined dietary and supplement calcium intake by white non-Hispanic men and women over 60 years of age was below the AI. The average calcium intake for women was 888 mg and 924 mg for men. Non-supplement users had even lower average calcium intakes (Ervin & Kennedy-Stephenson, 2002).

In the absence of nationally representative survey data for Canada, vitamin D intakes or vitamin D status cannot be accurately estimated (Whiting, Green, & Calvo, 2007). Data derived from Canadian studies of older adults showed dietary vitamin D intakes of 5.1 μg/day from food alone, and 8.7 to 9.0 μg/day when combined with routine supplement use were not adequate (Lee, Drake, & Kendler, 2002). Results from the longitudinal CaMos study, showed vitamin D intake (dietary and supplement) in women ages 51 to 70 years (n = 3,508) and over 70 years (n = 1,963) was 5.7(6.1) μg and 5.8(6.0) μg, respectively. For men ages 51 to 70 (n = 1,380) and over 70 years (n = 750), total vitamin D intake was 4.8(5.3) μg and 5.0(5.7) μg, respectively (Poliquin, et al., 2009). Since the current recommendations put forth by Osteoporosis Canada suggest at least 800 IU (20 μg) of vitamin D supplementation per day for adults over 50 years of age, these findings are staggering at less than half the recommended intake. It is evident that a large majority of the older adult population could benefit from both calcium and vitamin D supplementation and it seems prudent to ensure that all individuals over 50 years of age consume at least 1,200 mg of calcium and 800 IU of vitamin D per day.

2.3.3 Physical Activity

Physical activity is defined as “any bodily movement produced by skeletal muscles that results in energy expenditure…and can be categorized into occupational,
sports, conditioning, household, or other activities” and exercise as “a subset of physical activity that is planned, structured, and repetitive and has a final or an intermediate objective the improvement or maintenance of physical fitness” (Caspersen, Powell, & Christenson, 1985, pp. 126, 128). Physical activity, particularly activity that involves loading/impact is advocated for the prevention of osteoporosis. Specifically, weight-bearing exercise and strength training have been widely reported to play an important role in building and maintaining BMD and are also necessary for those with osteoporosis to reduce the risk of falls and subsequent fracture. Along with calcium and vitamin D intake, physical activity is an essential adjunct to drug treatment for the prevention and management of osteoporosis. Unfortunately, physical activity levels decrease as men and women age, with women being consistently less active than men. Specifically in Canada, there is a notable reduction in physical activity levels over the age of 65 years with approximately 60% of older adults deemed physically inactive (Warburton, et al., 2007).

There are many unresolved questions regarding what constitutes an optimal exercise program for bone health, specifically the optimal dose of exercise (intensity, frequency, and duration) needed to enhance bone strength (Hind & Burrows, 2007). Similar to muscle, bone responds to mechanical loading, or force on bones, which activates osteocytes and the BMU, and increases bone formation while decreasing resorption. Mechanically-induced strain is the key intermediary variable between loading and resulting bone formation; therefore, without mechanical strain (e.g., during bed rest), bone loss results (Murphy & Carroll, 2003). Mechanical strain greater than 1,500 to 2,000 με has been shown to stimulate bone formation (H. M. Frost, 1991). To put this
into context, exercise such as running results in approximately 800 με and jumping can generate strain greater than 1,600 με.

With regard to type of exercise, it is evident that dynamic weight-bearing and strength training are most effective for increasing BMD. Weight-bearing exercises such as walking, running, dancing, skipping, jumping, stair climbing, and sports that involve these activities (e.g., racquet sports, soccer) all involve bone and skeletal muscle of the legs and trunk working against the force of gravity while bearing weight of the body. Strength training exercises such as resistance exercises using free weights, weight machines, or exercise bands involve bone and skeletal muscle work by lifting, pushing, or pulling a given load or weight. Together, weight-bearing and strength training exercises are most effective pre- and peri- puberty resulting in enhanced BMD accrual. When carried out during mid-to-late adulthood, they result in attenuation of BMD loss. In postmenopausal women weight-bearing and strength training exercise has demonstrated to be effective in maintaining or increasing BMD at the lumbar spine and hip (Going, et al., 2003; Howe, et al., 2011; Wolff, Van Cronenbour, Kemper, Kostense, & Twisk, 1999). A recent updated meta-analysis reviewed 47 RCTs of exercise for preventing and treating osteoporosis in postmenopausal women. Results showed the most effective type of exercise intervention on femoral neck BMD was non-weight bearing high-force exercise such as progressive resistance strength training for the lower limbs (weighted mean difference of 1.03, 95% CI [0.24, 1.82]). The most effective intervention for BMD at the spine was combination exercise programs such as aerobics, walking, and resistance exercises (weighted mean difference of 3.22, 95% CI [1.80, 4.64]) compared with control groups (Howe, et al., 2011). The authors cited limitations of the meta-analysis were due
to the low quality reporting of the trials, particularly in the areas of allocation concealment and blinding. Another meta-analysis showed prescribed walking programs had significant positive effects on preservation of BMD at the femoral neck in postmenopausal women (Martyn-St James & Carroll, 2008).

In older men, Blumenthal et al. (1991) found significant increases in BMD after four to eight months of aerobic exercise. These results were consistent with those of older women. In addition, a meta-analysis found that site-specific exercise may help improve and maintain BMD of the femoral neck, lumbar spine, and os calcis in men over 30 years of age (Kelley, Kelley, & Tran, 2000). Therefore, exercise should be variable in nature for optimal bone health. Notably, there are very few RCTs of exercise effects on BMD, especially in men. Most intervention studies of the effects of physical activity on BMD in men are case–control and not randomized highlighting the need for large-scale randomized longitudinal trials. Recent results of the Osteoporotic Fractures in Men (MrOS) study showed older men ($N = 1,171, M_{age} = 77.2$ years) falling within the most physically active quartile had the highest bone strength index (a measure of bone compressive strength) and bone bending strength compared to men in the least physically active quartile (Cousin, et al., 2010).

Regular physical activity, particularly exercises that improve posture, balance, and strength, also reduce the propensity to fall, which is associated with fragility fracture (Gillespie, et al., 2012). This is especially important for frail older adults as it can improve quality of life by decreasing pain, and increasing the ability to perform activities of daily living, thus maintaining independence. Results from a recent meta-analysis showed Tai chi, a balance exercise, reduces risk of falling (Gillespie, et al., 2012). While
there are no prospective RCTs of exercise using fracture as an endpoint, a meta-analysis of 13 prospective cohort studies assessed the association between physical activity and hip fracture (Moayyeri, 2008). Results indicated moderate to vigorous physical activity was associated with hip fracture risk reduction of 45%, 95% CI [31, 56] and 38%, 95% CI [31, 44] respectively, among men and women.

The frequency and duration of exercise for increased bone formation is still under debate. However, studies have shown that the most effective types of strains are those that are high in rate, and have few loading cycles as bone becomes desensitized after 20 consecutive loading cycles (Lanyon, 1996; Turner & Robling, 2003). Recent studies have also suggested that resting between loading cycles can increase adaptive response mechanisms in bone (LaMothe & Zernicke, 2004). Over time, increased load increases BMD, and conversely, decreased load, or disuse over time decreases BMD. If exercise is stopped or reduced (with the exception of bone growth during childhood and adolescence) bone formation will not be maintained, although it is important to note there is a minimum bone mass that is genetically predefined. Similar with intake of calcium, exercise is essential for optimal bone health. In addition, the effect of mechanical loading on bone appears to be greater in individuals with lower initial bone mass than in those who are already active, with higher BMD (Skerry, 2008). Therefore, gains in BMD may be greater in sedentary individuals who begin exercise than in individuals who are active and increase their level of exercise.

Physical activity has also been shown to be most effective when combined with adequate calcium intake to maintain BMD. A meta-analysis of 17 randomized and nonrandomized trials in peri- and postmenopausal women suggested that physical activity
was more beneficial in increasing BMD in individuals with high calcium intakes (1,000 mg per day) than in those with lower calcium intakes (Specker, 1996). Furthermore, the combination of calcium and physical activity appears to be more effective in increasing bone mass or, at least, reducing bone loss in postmenopausal years than calcium alone (Prince, Devine, & Dick, 1995).

According to Canadian Society for Exercise Physiology (CSEP) recently revised physical activity guidelines, adults 50 years of age and older should engage in at least 150 min of moderate- to vigorous-intensity aerobic physical activity per week, in bouts of 10 min or more, in addition to muscle- and bone-strengthening activities that use major muscle groups, at least two days per week (Tremblay, et al., 2011). It is also recommended that older adults with poor mobility perform physical activities to enhance balance and prevent falls. Osteoporosis Canada physical activity recommendations for adults are the same as those put forth by CSEP, in addition to recommending balance training (e.g., Tai chi, pilates, and yoga) two to three days per week for a total of 120 minutes (Osteoporosis Canada, 2012).

2.3.4 Drug Treatment

From prevention to management of osteoporosis and related fracture, the primary goal is to intervene as early as possible to maintain BMD and preserve structural integrity of the skeleton. The purpose of drug treatment is to prevent progression of the disease in those identified as high or moderate risk, taking into consideration factors warranting consideration of treatment, ultimately reducing risk of fracture. Results from RCTs and meta-analyses demonstrate the efficacy and cost-effectiveness of drug treatment, particularly bisphosphonates, in attenuating bone loss and reducing risk of fracture at the
hip and spine in men and women with osteoporosis (Berger, et al., 2008; MacLean, et al., 2008; Sawka, et al., 2005). A recent study from the CaMos found that use of bisphosphonates, raloxifene, calcitonin, or hormone therapy was associated with attenuated bone loss in both men and women aged 50 to 79 years (Berger et al., 2008). A systematic review by the U.S. Preventive Services Task Force found women with low BMD have approximately a 40% to 50% reduction in fracture risk when treated with bisphosphonates (Nelson, Helfand, Woolf, & Allan, 2002).

Despite evidence demonstrating the efficacy of drug treatment for osteoporosis and related fracture, intervention is not optimal and the majority of individuals at high risk of fracture are left untreated, even among those who have suffered fracture (Elliot-Gibson et al., 2004). In Canada, less than 30% of individuals who experience osteoporotic fractures receive diagnosis or treatment for the disease (Giangregorio, et al., 2006; Papaioannou, et al., 2004; Papaioannou, et al., 2008). This was also highlighted in a study using the Quebec Health Insurance Authority database, with results showing only 25% of women over 70 years of age with fracture history were using some form of anti-resorptive drug therapy (Perreault, et al., 2005). There is a need for increased HCP awareness and usage of guidelines to identify fracture risk and the selection criteria for identifying those who would benefit from drug treatment. An integrated approach to management of osteoporosis and related fracture requires health behaviour change including physical activity and optimal calcium and vitamin D intake, in addition to risk assessment. After initial DXA screening, practice guidelines define categories of low, moderate, and high fracture risk to guide HCPs decisions for treatment. Those identified as “high risk” (10-year fracture risk > 20% or prior fragility fracture of the hip or spine or
> 1 fragility fracture) should be prescribed drug treatment (Papaioannou, et al., 2010). Many of those identified as “moderate risk” (10-year fracture risk 10% to 20%) should also be considered for drug treatment taking into consideration the following risk factors that are beyond those of the initial risk assessment (Papaioannou, et al., 2010):

- Additional vertebral fracture(s) (by vertebral fracture assessment or lateral spine radiograph)
- Previous wrist fracture in individuals over age 65 years and those with T-score \( \leq -2.5 \)
- Lumbar spine T-score < femoral neck T-score
- Rapid bone loss
- Men receiving androgen-deprivation therapy for prostate cancer
- Women receiving aromatase inhibitor therapy for breast cancer
- Long-term or repeated use of systemic glucocorticoids not meeting conventional criteria for recent prolonged use
- Recurrent falls (two or more in the past 12 months)
- Other disorders strongly associated with osteoporosis, rapid bone loss or fractures

Those identified as “low risk” (10-year fracture risk < 10%) would not require drug treatment and preventive health behaviours should be reinforced.

Currently, majority of drug treatments are anti-resorptive, and function by decreasing bone remodeling, more specifically, decreasing osteoclast activity. In Canada, treatments currently approved for management of osteoporosis and related fracture include the following (Osteoporosis Canada, 2012):

- Hormone therapy: Estrogens (brand names Premarin®, Ogen®, Estrace®, and others).
Bisphosphonates: Alendronate (brand name Fosamax®), Etidronate (brand name Didrocal®), Risedronate (brand name Actonel®), Zolendric acid (brand name Aclasta®), Fosavance ® (brand name Fosamax with vitamin D) and numerous generic versions.

Selective estrogen receptor modulators (SERMs): Raloxifene (brand name Evista®).

Calcitonin (brand name Miacalcin®).

PTH (brand name Forteo®).

Denosumab (brand name Prolia ™).

Hormone therapy (HT), specifically estrogen with or without progesterone, has been shown to have a beneficial effect on bone loss by improving BMD at the hip and spine, therein reducing the risk of fracture. In two separate meta-analyses of 22 and 13 randomized controlled trials, estrogen was associated with a 27% reduction in non-vertebral fractures and a 13% reduction in vertebral fracture respectively (Torgerson & Bell-Syer, 2001a, 2001b). Despite the benefits of HT for osteoporosis management, concerns with chronic use have been raised, notably based on findings from the WHI Clinical Trial that showed estrogen plus progesterone use increased risk of breast cancer, coronary heart disease, pulmonary embolism, stroke, and deep vein thrombosis in postmenopausal women (Rossouw, et al., 2002). Based on these results, it is recommended that other options for treatment be explored first.

Bisphosphonates are the most widely studied and prescribed drug for prevention and treatment of osteoporosis among men and postmenopausal women. Alendronate and risdronate have been shown to reduce the risk of hip and vertebral fracture in men and postmenopausal women (Boonen, et al., 2008; P. D. Miller, 2008). In addition to daily dosages, once-weekly, and once-monthly regimens have been developed in an attempt to
increase adherence. Cramer, Amonkar, Hebborn, and Altman (2005) found that once-weekly bisphosphonate use was associated with greater adherence in postmenopausal women than once-daily use (69% vs 58%, \( p < 0.001 \)) and had higher rates of treatment retention (44% vs 32%) after one year.

The SERM raloxifene is commonly prescribed to postmenopausal women, as is calcitonin, and both have been shown to increase BMD and reduce the incidence of vertebral fracture; however, there has been no evidence that they reduce the incident of non-vertebral or hip fractures (Ettinger, et al., 1999). Calcitonin may also play a role in the treatment of osteoporosis in men, although this has not been firmly established. In addition, PTH works by stimulating osteoblast activity and thus bone formation; however, it should not be taken for longer than a 24 month period. Denosumab is a new class of anti-resorptive osteoporosis treatment shown to reduce risk of fracture at the spine and hip in postmenopausal women (Josse, Khan, Nqui, & Shapiro, 2013). Clinical trials are ongoing in men (Osteoporosis Canada, 2012).

Currently, Canadians without a private or employer health plan or sufficient personal resources may be eligible for coverage by publicly funded provincial or territorial drug plans. However, access to medications through these public drug plans varies across Canada, and is severely restricted in some provinces. In Saskatchewan, seniors aged 65 years and older, depending on net income, pay up to $20 per prescription for drugs listed on the Saskatchewan Formulary and those approved under Exception Drug Status (Government of Saskatchewan Ministry of Health, 2012). Osteoporosis drug treatment access varies in Saskatchewan, with PTH inaccessible, and SERMs, denosumab, calcitonin, and bisphosphonate access restricted, with the exception of
etidronate which has open access (Osteoporosis Canada, 2012). Restricted access (Exception Drug Status) implies these drugs are covered by the provincial drug plan but require special authorization from the plan, or require prescriber or pharmacist to apply on behalf of their patients indicating how specific medical criteria are met (i.e., the patient must meet certain medical criteria). Based on analysis of the availability of osteoporosis medications through provincial/territorial public drug plans, Osteoporosis Canada gave Saskatchewan a “C” grade (Jiwa, et al., 2008). The bisphosphonates, alendronate and etidronate have generic brands available that are cheaper and just as effective. Notably, alendronate lost patent protection in Canada in 2005, which resulted in approximately a 40% reduction in its average wholesale price. Taking these price reductions into consideration, the cost-effectiveness of alendronate therapy has improved, making it more cost-effective for the overall health care system.

The Canadian Institute for Health Information (CIHI) reported on trends in bisphosphonate use by men and women over 65 years of age from 2001 to 2007 using drug claims data from Alberta, Saskatchewan, Manitoba, New Brunswick, Nova Scotia, and Prince Edward Island (Canadian Institute for Health Information, 2009). Total drug program expenditures for bisphosphonates based on paid claims in all provinces except P.E.I. (data unavailable), increased at an annual average rate of 12.7% from 2001 to 2007. This increase may be a result of the Scientific Advisory Council for Osteoporosis Canada releasing clinical practice guidelines in 2002 (Brown & Josse, 2002). In Saskatchewan, the rate increased yearly, with the exception of 2006 to 2007 when it remained stable. Bisphosphonate use in 2006-2007 was more than six times higher in women (20.4%) than men (3.3%). While this may reflect the fact that osteoporosis is
more prevalent in older adult women, it may also suggest HCPs are severely under-diagnosing, and therefore under-treating osteoporosis and fracture risk in older adult men.

Despite proven efficacy of osteoporosis drug treatments, once a recommendation and decision has been made to initiate drug treatment, adherence to the prescribed treatment presents an issue. Siris, Harris, and Rosen (2006) estimated that improved adherence to drug therapy could reduce fractures by approximately 25%, yet of 35,000 women who received bisphosphate prescription, 57% prescribed daily or weekly doses were noncompliant, and 80% were nonpersistent within two years of initiation. It is evident there is a need to educate both men and women on treatment for optimal bone health and to ensure treatment recommendations are made by HCPs when necessary.

### 2.4 Detection of Osteoporosis: Screening and Diagnosis

Although DXA screening is only one, initial component of a multifaceted approach to osteoporosis and fracture risk prevention and management, it is an important one. The primary goal of osteoporosis screening is to decrease disease specific morbidity and mortality. The prevention of osteoporosis and related fractures can be classified into three levels, including primary, secondary, and tertiary prevention. While tertiary prevention involves the medical and treatment approaches to minimize complication once a disease has progressed (e.g., drug treatment for osteoporosis), screening is a part of many primary and all secondary prevention activities. Primary prevention of osteoporosis involves activities to prevent disease prior to its occurrence. This includes risk factor screening tools which aid HCPs in identifying individuals at risk of low BMD who should be referred for DXA screening. Secondary prevention is the early detection to stop or modify the extent of a disease. Presently, DXA is the most widely accepted method for
detecting osteoporosis. The WHO fracture risk assessment tool (FRAX™) is a newly developed form of secondary prevention and uses clinical risk factors, including fracture history to determine absolute fracture risk.

2.4.1 Dual Energy X-ray Absorptiometry

The gold standard method for diagnosing osteoporosis and estimating fracture risk is DXA. DXA is non-invasive, has low radiation exposure, and provides an accurate and precise measurement of BMD at the femoral neck, spinal vertebrae, wrist, and total body (Brown & Josse, 2002). During DXA measurement, an individual lies on a padded table of the machine with an x-ray generator located below the individual and an imaging device positioned above. The DXA machine sends an invisible beam of low-dose x-rays with high and low energy peaks through the bones being examined. High energy is absorbed primarily by soft tissue and low energy by bone. DXA machines feature special software that compute and display BMD measurements on a computer monitor.

DXA measures bone mineral content (g) which represents total mass of an area scanned. When divided by the area measured, a value for BMD (g/cm²) is derived which measures areal density. DXA does not measure bone size or assess bone quality (e.g. microarchitecture, bone turnover) that are also main determinants of bone strength. The size of bone can affect BMD; thus, improving BMD results as a predictor of fracture risk as bone size is also a determinant of skeletal strength (Kanis, et al., 2002). This is especially true for men as they typically have larger bone size compared to women.

The World Health Organization (WHO) has defined criteria for diagnosing osteoporosis and assessing risk of fracture using DXA screening. A BMD value at the spine or hip that is more than 2.5 SDs below the optimal mean for healthy young
individuals of the same race and gender defines an individual as having osteoporosis (T-score ≤ -2.5). The T-score criterion has been widely accepted by organizations such as the International Osteoporosis Foundation (IOF) and Osteoporosis Canada as both a diagnostic and intervention threshold. Osteopenia is defined as a BMD between 1.0 and 2.5 SDs below the optimal mean (-2.5 < T-score < -1.0), and an individual with normal BMD is defined as being no more than 1.0 SD below the optimal mean BMD (T-score ≥ -1.0) (Kanis, Melton, Christiansen, Johnston, & Khalsaev, 1994).

Measurement of BMD at the hip is the gold standard for diagnosing osteoporosis in terms of skeletal site as it is the most severe of all fractures in terms of morbidity and mortality, and has the highest predictive value for fracture at any site compared to measurements at the spine, wrist, or total body (Marshall, Johnell, & Wedel, 1996; Papaioannou, et al., 2010). Other sites are useful for risk assessment of osteoporosis rather than diagnosis. Since the WHO classification was developed for use in postmenopausal Caucasian women, suitable diagnostic criteria are less well defined in men and other ethnicities. However, studies indicate the same criteria for hip BMD (T-score ≤ -2.5) in women can be used in the diagnosis of osteoporosis in men (Kanis & Gluer, 2000).

The purpose of DXA screening is to assist with fracture risk assessment, target interventions accurately for individuals at low, moderate, and high risk, and monitor change in BMD. The efficacy and effectiveness of screening is one of the most important questions in medical and health research. Efficacy relates to whether the intervention works (i.e., detects individuals with osteoporosis) under ideal conditions. Efficacy trials are characterized by strict, standardized control and provide evidence regarding the
efficacy of a screening test by establishing a causal relationship. Effectiveness relates to the usefulness of screening (i.e., correctly identifying individuals with osteoporosis) in real-life situations and populations, such as routine clinical practice. Although characteristics of successful efficacy research (e.g., intensive, standardized) are fundamentally different from population-based effectiveness trials (e.g., broad appeal, adaptable to settings), both are important in screening tests. Research groups in public health have long proposed a screening test proven to be efficacious may be more effective in clinical practice (R. E. Glasgow, Lichtenstein, & Marcus, 2003). Therefore, for a screening test to have a broader public health impact, it must be both efficacious and have high reach (R. E. Glasgow et al., 2003). However, effectiveness trials are expensive and often difficult to investigate. The results of meta-analyses assessing efficacy make it possible to hypothesize on the potential effectiveness of screening.

Several well-controlled prospective studies using DXA indicate that as BMD decreases, risk of fracture increases exponentially; specifically, for each standard deviation reduction in BMD, there is an estimated 2-fold increase in fracture risk (Klotzbuecher, et al., 2000; P. D. Miller, et al., 2002). A meta-analysis by Marshall, Johnell, and Wedel (1996) found the pooled relative risk (RR) for one standard deviation decrease in BMD at the femoral neck was 2.6 (95% CI [2.0, 3.5]). One of the largest and most informative studies was the 10-year follow-up Study of Osteoporotic Fractures (SOF) involving 9,704 Caucasian women over 65 years of age (Stone, et al., 2003). Results of the study confirmed the association between BMD and risk of fracture with a high statistical reliability for different types of fracture. The prediction of hip fracture risk from hip BMD measurement using DXA had the largest RR of 2.4 (95% CI [2.11, 2.83]).
The most recent and largest meta-analysis was conducted by Johnell et al. (2005) in which the authors evaluated 9,891 men and 29,082 women from 12 cohorts including CaMos and EPIDOS among others. Results indicated BMD measurement at the femoral neck using DXA was a strong predictor of hip fractures in both men and women. In men and women over 65 years of age, RR was 2.94 (95% CI [2.02, 4.27]) and 2.88 (95% CI [2.31, 3.59]), respectively for each standard deviation decrease in BMD. Results also showed in men and women at any given age (≥ 50 years), 10-year hip fracture probability increased with decreasing T-score. This suggests that hip BMD can be used to determine long-term fracture probabilities. This was an important finding and largely contributed to the use of BMD in the WHO FRAX™ model. It is important to note there is no threshold for fracture below which fracture risk suddenly increases. Therefore, BMD is best described as a continuous risk factor, whereby the lower the BMD, the higher the risk of fracture (Cummings, Bates, & Black, 2002). Based on the findings from the meta-analyses discussed, variations in predictive value with age and the BMD measurement site should be taken into consideration when BMD is used as a measure of fracture risk.

Despite evidence demonstrating the efficacy of DXA screening for diagnosing osteoporosis and predicting fracture risk, several common concerns of DXA screening and its predictive ability have been raised. Ideally, a screening test should have high sensitivity and high specificity. Sensitivity is the proportion of true positives among the total number of positive test results (e.g., correctly identifying individuals who have low BMD). Specificity is the proportion of true negatives among the total number of negative test results (e.g., correctly identifying individuals who do not have low BMD) (Walter, 2005). The performance characteristics are less than optimal with regard to sensitivity.
and specificity of DXA screening. DXA has been shown to have high specificity but low sensitivity suggesting BMD measurements alone may not be optimal for detecting individuals at high risk of fracture (Kanis, Johnell, Oden, Johansson, & McCloskey, 2008). Thus, risk of fracture is very high when osteoporosis is present, but not necessarily negligible when BMD is normal. This is one reason why population screening with DXA for all asymptomatic men and women over 50 years of age is not recommended by many organizations including the WHO, IOF, and Osteoporosis Canada. Rather, these organizations recommend screening based on age and other identified risk factors. Notably, osteoporosis is a multifactorial disease; therefore, BMD can only capture one aspect of the likelihood of fracture outcome. Studies have shown that clinical risk factors such as age and fracture history influence osteoporosis and related fracture risk independently of BMD; more specifically, they improve the sensitivity of BMD for any specificity (Kanis, 2002). This was the main premise for the development of FRAX™. Based on a series of meta-analyses, the WHO identified clinical risk factors for fracture (sex, age, BMI, prior fracture history, parental history of hip fracture, prolonged glucocorticoid use, rheumatoid arthritis, current smoking, and alcohol intake of three or more units daily) that provide independent information on fracture risk, and combined these with BMD T-score at the hip to develop FRAX™ (Kanis, et al., 2008). FRAX™ is an algorithm that calculates 10-year absolute risk of hip or other osteoporotic fracture in men and women over 50 years of age. This time period covers the probable duration of treatment and benefits that may continue once treatment is stopped. Currently, FRAX™ is available in Canada for use and has been calibrated using Canadian fracture data and validated in Canadians (Leslie, Tsang, & Lix, 2009).
Other drawbacks of DXA screening are the limited availability of DXA machines, cost of the machines, cost and availability of trained technicians required for machine operation, and the need for physician referral and waiting lists. The Canadian health care system provides insurance coverage for all medically necessary HCP, laboratory, and hospital services. However, despite universal health care, practice guidelines for identifying who should be screened, and demonstrated efficacy of screening, very few Canadians at high risk are being referred. Based on analysis of current osteoporosis screening rates across Canada, Osteoporosis Canada gave most provinces a “C” grade or lower, with Saskatchewan receiving a failing grade for inadequate access to DXA screening (Jiwa, et al., 2008). Similarly, the Health Quality Council report on BMD testing services in Saskatchewan in 2001 indicated DXA screening services were insufficient to meet increased need (Health Quality Council, 2003). Ultimately, if older adults are not being screened, they may be less likely to engage in health behaviours such as drug treatment, calcium and vitamin D intake, and weight-bearing exercise for osteoporosis prevention and management. In Saskatchewan, only three DXA screening sites currently operate. Performance measures of DXA screening wait times in Regina and Saskatoon showed the target time for a patient to receive an elective DXA screening was within 90 days (Government of Saskatchewan, 2012). From 2005 to 2008, wait times decreased yearly with Regina meeting the target 90 days in 2007 to 2008 while in Saskatoon wait times reached approximately 125 days for DXA screening (Saskatchewan Health, 2008). Based on the Health Quality Council report, the rate of testing for women aged 65 years and over was 8.3 per 1,000 compared to 0.6 per 1,000 for men suggesting men with major risk factors are not being screened for osteoporosis. In addition, during
the two month study period, the average wait time for screening was 141 days (Health Quality Council, 2003).

Based on 2001 Canadian Census information, approximately 436,000 women and 138,000 men 65 years of age and older were unaware they had osteoporosis of the hip or spine (Sawka, et al., 2006). However, results from the 2003 CCHS show nearly all older adults (96%) had a regular doctor, of which 88% had consulted a general practitioner at least once in the past year (Statistics Canada, 2006). This evidence suggests HCPs are simply not identifying or referring at-risk individuals for DXA screening. The lack of such geriatric-informed standards of care may be leading to older adults being under-diagnosed and untreated for osteoporosis. If HCPs are unaware of the seriousness of osteoporosis and related fracture risk and fail to follow screening and diagnosis guidelines, then not only are they less likely to recommend appropriate health behaviours for prevention and management of the disease, and treat those at high risk, but improvements in health policy to make osteoporosis a priority in health care are less likely to occur.

As previously described in Section 2.3 (Table 1), identifying Canadians who should undergo DXA screening in is based on established practice guidelines. The guidelines propose routine DXA screening for osteoporosis risk factor indicators (e.g., age 65 years and older, parental hip fracture, current smoking, etc.) in men and women over 50 years to identify those at high risk who should undergo screening (Papaioannou, et al., 2010). When followed in clinical practice, these guidelines help reduce undue demand placed on DXA screening. It is still unclear how often DXA screening should be performed in individuals who are receiving treatment or in those who are not. Currently,
national guidelines recommend DXA screening be repeated every one to three years for individuals receiving treatment (Papaioannou, et al., 2010). However, findings by Berger et al. (2008) suggest that the average change in BMD over two to three years is small and comparable to measurement errors in DXA screening. Therefore, it is debatable whether individuals already receiving treatment for osteoporosis should undergo follow-up screening at all based on the efficacy of osteoporosis drug therapy for managing osteoporosis and reducing related fracture. For moderate-risk individuals, including those with T-score ≤ -2.5, a one to three year repeat screening is also recommended to monitor bone loss (Papaioannou, et al., 2010). For low-risk individuals with few risk factors for osteoporosis, BMD measurement every five to 10 years has been deemed sufficient (S. A. Frost, Nguyen, Center, Eisman, & Nguyen, 2009).

While prospective studies have demonstrated the efficacy of osteoporosis screening, they suggest, but do not prove, that DXA screening reduces fracture rates. Currently, there is no direct evidence of the effectiveness of DXA screening for reducing the osteoporosis related fracture burden in a population. No RCTs evaluating the effects of screening on fracture outcomes have been conducted. As a result, it is unclear whether early detection will lead to a reduction in population-based mortality. However, one observational study demonstrated men and women over 65 years of age who underwent DXA screening, including those with normal and below-normal results, had a lower femoral neck fracture rate (36%) than those who did not receive screening (Kern, et al., 2005). This reduction may be partly due to confounding factors (e.g., treatment use) that influence fracture risk but were not included in the analyses.
2.4.2 Calcaneal Quantitative Ultrasound

Although osteoporosis screening by DXA is the gold standard method, there is increased interest in the use of other screening methods including calcaneal QUS. Compared to DXA, QUS is radiation-free, fast, portable, less time-consuming, and can be performed at a considerably lower unit cost ($20,000 per unit compared to approximately $100,000 for DXA unit); thus, it is practical for use in the community. In addition, a recent meta-analysis showed QUS can predict hip fracture in elderly men and women independent of risk estimates from DXA (Moayyeri, et al., 2012). While QUS has the potential to increase DXA screening efficiency and cost-effectiveness by reducing the number of individuals referred for DXA who are otherwise healthy, or identifying individuals at high risk of fracture who should receive treatment, its clinical use is less well defined. Currently, there are no universal guidelines for diagnostic cut-offs, and the accuracy of QUS in identifying osteoporosis remains unclear.

Ultrasounds are sound waves beyond the audible threshold that alter with regard to their shape, intensity, and speed upon contact with bone. Therefore, bone tissue may be characterized in terms of ultrasound velocity and attenuation. Measured parameters include both broadband ultrasound attenuation (BUA, in dB/MHz) that measures frequency dependence of ultrasound attenuation, and speed of sound (SOS, m/s) that measures transmission velocity (m/s) of ultrasound passing through soft and bone tissue. These results, depending on the model, can be combined and expressed as a stiffness index (SI), which is compared to young adult and age-matched references to provide a T-score to simplify interpretation (Krieg, et al., 2008). The most validated device is the Achilles Lunar ultrasound (GE Medical, USA) and can be classified as trabecular.
transverse transmission, meaning the ultrasound waves travel through trabecular bone. This device uses water-based or direct-contact systems (coupling medium as gel) at the calcaneus (heel) and focused or unfocused transducers to obtain measured parameters.

The reliability and validity of QUS in distinguishing those with osteoporosis and those with a normal BMD remain questionable. A meta-analysis from 2006, evaluated the accuracy of QUS for identifying individuals with osteoporosis (DXA T-score ≤ -2.5) (Nayak, et al., 2006). Results showed sensitivity of 33% and specificity of 93%, suggesting QUS performed poorly in correctly identifying individuals with osteoporosis, but was effective in correctly identifying individuals with normal BMD. Notably, official positions on QUS in the management of osteoporosis developed by the International Society for Clinical Densitometry (ISCD) advise against the application of the WHO T-score classification of osteoporosis to QUS due to variations in measurements by skeletal site and device model (Hans & Krieg, 2009). Studies included in the review primarily assessed women, but varied in age group and ethnicity. The studies also varied in use of device manufacturer, QUS parameters, and measured DXA and achilles site.

Studies using the Achilles Lunar ultrasound (GE Medical, USA) in men and women with mean age over 50 years show QUS and DXA are moderately correlated \( r = 0.288 \) – 0.694) at the spine or femoral neck (Bachman, Crewson, & Lewis, 2002; Collinge, Lebus, Gardner, & Gehrig, 2010; Edelmann-Schafer, Berthold, Stracke, Luhrmann, & Neuhauser-Berthold, 2011; Gemalmaz, Discigil, Sensoy, & Basak, 2007; Sorensen, et al., 2001). Notably, majority of the study populations’ age range included men and women less than 50 years, and the two studies including men did not evaluate
genders separately. For QUS parameters to be reliably applied the impact of age and sex on the relationship between QUS and DXA must be defined.

The diagnostic of QUS is determined by receiver operating characteristic (ROC) curves and computation of the area under the curves (AUC). AUCs greater than 0.70 suggest a screening test is efficient, and an AUC greater than 0.90 indicates high diagnostic accuracy (Streiner & Cairney, 2007). Previous studies assessing the diagnostic accuracy of QUS in older women (AUC of the femoral neck = 0.82-0.91 vs. AUC of the spine = 0.71) suggest it may be most useful in predicting high risk of low BMD at the femoral neck (Edelmann-Schafer, et al., 2011; Sorensen, et al., 2001). Other studies have also evaluated the performance of QUS and found approximately equivalent or marginally lower AUCs; however these studies varied in population and design (e.g. combined analyses of men and women, ages ranging from young to old, and retrospectively collected data) (Collinge, et al., 2010; Pearson, Masud, Sahota, Earnshaw, & Hosking, 2003). Few studies have addressed the diagnostic accuracy of QUS in men. One study combining men and women found an AUC of 0.84 at the hip (Collinge, et al., 2010). In men alone, Mulleman et al. (2002) found a QUS SI yielded an AUC of 0.74 in those \( n = 66, M_{\text{age}} = 52 \) years) who had sustained fracture. Overall, while the relationship between low BMD and fracture risk holds true in men, and current evidence suggests QUS may perform similarly in men and women, the diagnostic accuracy of QUS in men remains unclear.

The ISCD has indicated a need for pre-defined diagnostic cut-offs of specific populations by sex, age, and ethnicity based on SI results falling above and below thresholds where, ideally, sensitivity and specificity exceeds 90%, respectively (Hans &
Krieg, 2009). Currently, cut-offs proposed in the research literature are limited for both older men and women. However, one promising study by Hans and Krieg (2009) evaluated 5,954 women aged 75 years and older taking part in the EPIDOS Study (France) used the 90% threshold approach. They found a high diagnostic accuracy of the Achilles Lunar QUS with SI ≤ 57 and low likelihood of osteoporosis with SI > 78 in postmenopausal women. Other studies have reported much lower T-score cut-offs to reach 90% sensitivity and specificity; however these studies had limitations including small sample sizes, varying age groups, and/or BMD site measured (Edelmann-Schafer, et al., 2011; Gudmundsdottir, Indridason, Franzson, & Sigurdsson, 2005; Pearson, et al., 2003).

Although DXA remains the accepted gold standard for assessing BMD, due to inadequate access to DXA screening and progressing aging population, pre-screening individuals with QUS may contribute to early identification of men and women at risk of osteoporosis who should be referred for DXA screening. This may be carried out using pre-defined, device-specific thresholds of specific populations defined by sex, age, and ethnicity based on SI results falling below a threshold where specificity and sensitivity exceeds 90%. No studies have identified potential diagnostic cut-offs in Canadian men and women over 50 years of age; thus, there is a need to determine the efficacy of QUS in screening both men and women at risk of osteoporosis.

2.4.3 Clinical Risk Factor Assessment Tools

In addition to the traditional and new screening devices, several clinical risk factor assessment tools have been developed and validated for their efficacy in detecting older men and women at increased risk of low BMD (McLeod & Johnson, 2008). These
tools have potential benefits for HCPs to assist in their decision making regarding individuals who would benefit most from DXA screening as well as increase screening efficiency and cost-effectiveness by reducing the number of individuals referred who are otherwise healthy. Although it is ideal to screen BMD using DXA on the basis of clinical guidelines, it is not practical from a public health perspective.

Through a simple evaluation of risk factors associated with osteoporosis, several risk factor screening tools using various algorithms have been developed and validated for their efficacy in detecting postmenopausal women at increased risk of low BMD. The most commonly used screening tools include the Osteoporosis Self-Assessment Tool (OST), the Simple Calculated Osteoporosis Risk Estimation (SCORE), the Osteoporosis Risk Assessment Instrument (ORAI), the body weight criterion (BW), the Osteoporosis Index of Risk (OSIRIS), and Age, Body Size, No Estrogen (ABONE) (Cadarette, et al., 2000; Koh, et al., 2001; Lydick, et al., 1998; Michaelsson, et al., 1996; Sedrine, et al., 2002; Weinstein & Ullery, 2000). Common risk factors used in the screening tools’ algorithms include age, body weight, HT use, and fracture history.

It is important that osteoporosis risk factor screening tools are accurate and efficacious in determining those at risk. A systematic review of these common, validated osteoporosis risk factor screening tools was conducted to assess the performance of these assessment tools in determining postmenopausal women at high risk of low BMD who should be referred for DXA screening (McLeod & Johnson, 2008). The OST has undergone extensive validation in postmenopausal women and has demonstrated better discriminative performance with use of only two risk factors, age and body weight in its
algorithm, compared to SCORE, ORAI, BW, OSIRIS, and ABONE. The review focused on postmenopausal women as similar data are lacking for men (Table 2).
Table 2

*Algorithm and Threshold Value for the Osteoporosis Self-Assessment Tool (OST)*

<table>
<thead>
<tr>
<th>Screening tool</th>
<th>Target population</th>
<th>Cut-off score</th>
<th>Risk factors</th>
<th>Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>OST</td>
<td>Identify postmenopausal women likely to have femoral neck T-score ≤ -2.5</td>
<td>&lt; 2</td>
<td>Age, body weight (kg)</td>
<td>[0.2 (weight in kg – age)] truncated to an integer</td>
</tr>
</tbody>
</table>

*a* Original OST was based on threshold scores developed and validated for Asian postmenopausal women. OST has since been validated in Caucasian women yielding a threshold score of < 2.
A meta-analysis assessing the performance of OST found it performed moderately (summary likelihood ratio of negative test result, sLR- = 0.19, 95% CI, 0.17-0.21) in excluding postmenopausal Caucasian women with femoral neck T-score ≤ -2.5, but poorly (sLR- = 0.43, 95% CI 0.31-0.43) when excluding lumbar spine T-score ≤ -2.5 (Rud, Hilden, Hyldstrup, & Hrobjartsson, 2007). An update of this meta-analysis found OST accuracy was higher at the femoral neck in white postmenopausal women compared to other risk factor assessment tools (Rud, et al., 2009). However, several limitations of the methodological quality of the studies including the use of retrospective data, and inadequate reporting of study sample characteristics, withdrawals, and uninterpretable test results were evident (Rud, et al., 2007, 2009).

The OST was first developed and validated in postmenopausal women from eight Asian countries but has since been applied to postmenopausal Caucasian women and older men. The performance of OST in Caucasian peri- and postmenopausal women identifying femoral neck T-score ≤ -2.5 using a cut-off < 2 showed sensitivity of 92%, specificities ranging from 37% to 71%, and AUC of 77, indicating it may be a useful tool in detecting those with low BMD but less reliable in detecting those with normal BMD (Richy, Gourlay, et al., 2004; Rud, et al., 2005). Very few studies have validated OST in men. Adler, Tran, and Petkov (2003) determined the accuracy of OST in 181 men (124 Caucasian, 54 black, 3 other) with a mean age of 64.3 years, recruited from pulmonary and rheumatology clinics. None of the men had been previously screened for osteoporosis. Using an OST cut-off < 3, high risk of osteoporosis was predicted with a sensitivity of 93%, specificity of 66%, and AUC of 0.814. Regardless of ethnicity, the predictive value was maintained. Skedros, Sybrowsky, and Stoddards (2007) found that
OST with a cut-off ≤ 2 identified Caucasian men (N = 158, M_{age} = 67.5 years) likely to have lumbar spine, hip, or femoral neck T-scores ≤ -2.5 with a sensitivity of 85%, a specificity of 65%, and an AUC of 0.81. Overall for clinical practice, the OST may provide a quick and easy means of determining individuals who would most benefit from DXA screening, while still maintaining discriminatory abilities equivalent to those of more expensive, and complex screening tools; however more research is needed.

While neither QUS nor OST can be used to diagnosis osteoporosis based on the WHO definition, they may be useful pre-screening tools to identify men and women at increased risk of osteoporosis and related fracture who should be referred for DXA screening, in addition to improving screening efficiency. Despite studies validating QUS and OST, there is limited evidence of the comparative discriminative performance of these tools for identifying osteoporosis in men and women. Cook, Collins, Tucker, and Zioupos (2005) examined the sensitivity and specificity of eight risk factor screening tools, including OST and calcaneal QUS using the CUBA device and their ability to identify 208 postmenopausal women at risk of osteoporosis compared to DXA. T-scores from DXA identified 21.6% of the women as osteoporotic at the total hip or lumbar spine. QUS correlated best with DXA at the hip (r = .650, p < 0.001) compared to OST (r = .633, p < 0.001). QUS and OST had a significant but moderate correlation (r = .515, p < 0.001). The AUC was 76.6% and 71.6%, respectively for QUS and the OST indicating they were both potentially useful screening tools for identifying postmenopausal women with hip and lumbar spine T-scores ≤ -2.5. Notably, the CUBA device is not as widely validated and uses different measurement parameters compared to the Achilles Lunar QUS. Rud et al. (2009) found QUS SI (Achilles Lunar, GE Medical) was more accurate
than OST regardless of BMD site in white postmenopausal women; however, these studies were reported as abstracts. Given the limited studies, it is necessary to compare the accuracy of QUS and OST to DXA in older men and women.

2.4.4 Ethical Implications of Screening

Ethics plays an important role in the evaluation of screening tools. A screening tool proven to be efficacious in clinical trials is necessary to demonstrate whether it will work; however, its effectiveness in clinical practice is also important to determine its usefulness in public health, such as population-based screening. In addition, from an ethics and health policy standpoint, it is important that screening techniques, particularly diagnostic screening techniques, are cost-effective especially due to the marked rise in the aging population.

Currently, there are no longitudinal RCTs proving the effectiveness of DXA screening. Thus, while prospective studies have shown DXA screening strongly predicts fracture, and clinical trials have proved treatment reduces the risk of fractures, this evidence suggests, but does not prove, that DXA screening reduces fracture rates. However, the lack of evidence should not deter HCPs from applying evidence-based guidelines. The specific selection and diagnostic guidelines, demonstrated efficacy, and the favourable cost-effectiveness warrant osteoporosis screening. In addition, utilizing pre-screening techniques for osteoporosis and related fracture such as QUS and the OST may improve the usefulness of DXA screening. FRAX™, the newest development and shift in osteoporosis-related fracture assessment is considered a more accurate way to describe effectiveness of a screening intervention; however, further research is still needed. In a recent systematic review, the shift in the management of osteoporosis by
screening for fragility fracture risk based on FRAX and its performance was challenged. The authors found that simple clinical risk factor assessment tools including the OST and ORAI performed as well, or better than the more complex FRAX in predicting osteoporotic fractures (Kanis, et al., 2008; Rubin, Friis-Holmberg, Hermann, Abrahamsen, & Brixen, 2013).

Several studies have performed detailed analysis demonstrating the favourable cost-effectiveness of osteoporosis screening (Schousboe, Ensrud, Nyman, Melton, & Kane, 2005; Schousboe, et al., 2007). The cost-effectiveness of screening is subject to the number of individuals requiring screening, the cost of the screening test, and the cost of drug therapy for those detected at risk (Sawka, et al., 2006). Due to the rise in the aging population, the cost-effectiveness of osteoporosis screening is imperative. Schousboe et al. (2007) determined the lifetime costs per quality-adjusted life year (QALY) gained for DXA screening followed by five years of bisphosphonate therapy in men 65 years of age and older with femoral neck T-score ≤ -2.5. Results showed lifetime cost per QALY for men with a fracture history and men 80 years and older without a prior fracture was less than $50,000. This screen-and-treat strategy was sensitive to bisphosphonate cost, efficacy, fracture rates, and medication adherence. A similar study in postmenopausal women showed universal DXA screening combined with alendronate therapy for those diagnosed with osteoporosis was highly cost-effective even under assumptions of reduced adherence to drug therapy (Schousboe, et al., 2005). Lifetime cost per QALY was $43,000 for women 65 years of age, and $5,600 per QALY gained for women 75 years of age. Notably, alendronate lost patent protection in Canada in 2005 and in the United States in 2008. In Canada, this resulted in approximately a 40% reduction in its average
wholesale price. Taking this price reduction into consideration, the cost-effectiveness of alendronate therapy will improve, thus providing even more cost-savings for both the individual and the overall health care system.

In addition to DXA screening, studies have evaluated pre-screening methods such as QUS and clinical risk factor assessment tools as cost-effective approaches to reduce the economic burden of osteoporosis screening (Kraemer, Nelson, Bauer, & Helfand, 2006; Mueller & Gandjour, 2008; Richy, Ethgen, Bruyere, Mawet, & Reginster, 2004). Pre-screening with QUS followed by DXA, identified fewer postmenopausal women to treat, prevented more hip fractures, and was more cost-effective than screening with DXA alone (Kraemer, et al., 2006; Mueller & Gandjour, 2008). Richy, Ethgen, Bruyere, Mawet, and Reginster (2004) compared the cost-effectiveness of screening tools in 4,035 postmenopausal Caucasian women. Results showed pre-screening with SCORE, OST, and ORAI, with cut-off scores indicating medium and high risk of osteoporosis, identified 75% to 89% of women with a consistently reduced cost for each individual detected. Another study in 70 year-old men compared the treatment benefits and costs associated with DXA screening alone, to pre-screening using the OST followed by DXA screening (Ito, Hollenberg, & Charlson, 2009). Results showed it was much more cost-effective to risk-stratify using the OST and perform DXA screening on those identified as high risk, followed by alendronate therapy for those diagnosed with osteoporosis. These results have great implications for public health regarding the usefulness of screening tools in alleviating the economic burden of DXA screening. While screening is necessary for reducing fracture risk, it may be more practical and cost-effective to pre-screen with a tool shown to have high efficacy followed by DXA screening on older adults at high risk,
rather than perform population-based screening on all men and women over 65 years of age, including those who may have normal BMD.

Despite universal health care in Canada, the recommended guidelines for identifying who should be screened, and many prospective studies demonstrating the efficacy of screening, very few at-risk Canadians are being screened. There is a need to improve screening in older adult men and women in Canada and address the factors (e.g. access to screening, health promotion, social disparities) contributing to the under-diagnosis and under-treatment of older adults. If older adults are not being screened, they may be less likely to engage in health behaviours. The following section will discuss the influence of DXA screening on health behaviours including calcium and vitamin D intake, physical activity, and drug treatment initiation for osteoporosis prevention and management.

2.5 Influence of DXA Screening on Health Behaviours

Maintaining bone health requires an integrated approach to prevention and management of osteoporosis and its related fractures. This approach, as outlined in the Canadian clinical practice guidelines, requires timely DXA screening for those at risk, preventive health behaviour modification in men and women over age 50, and/or appropriate drug treatment based on fracture risk (Papaioannou, et al., 2010). As previously discussed, the most common modifiable health behaviours encouraged for prevention and management of the disease include adequate daily calcium and vitamin D intake (1,200 mg and 800 to 2,000 IU, respectively) and regular physical activity. Several meta-analyses have documented the beneficial effects of these health behaviours on osteoporosis and fracture risk reduction (Boonen, et al., 2007; Howe, et al., 2011;
Prentice, et al., 2012; Tang, et al., 2007). In addition, there is consistent evidence that drug treatment options available in Canada, including both antiresorptive agents and bone-forming agents, are effective in reducing risk of fracture in men and women with osteoporosis (MacLean, et al., 2008; Murad, et al., 2012).

DXA screening is a critical and initial component of practice protocol for osteoporosis risk reduction informing clinical decisions and recommendations for prevention and management, in addition to patient health behaviour change. Consequently, if individuals at risk are not being screened, or if individuals are screened, but unaware of their results, they may be less likely to engage in health behaviours to prevent and manage the disease. The studies reviewed evaluate the influence of DXA screening on health behaviours including calcium and vitamin D intake, physical activity, and drug treatment in men and women.

2.5.1 Change in Calcium and Vitamin D Intake

Calcium and vitamin D intake are traditionally the primary focus for prevention and management of osteoporosis, both prior and subsequent to DXA screening. Rubin and Cummings (1992) were the first to determine the effects of DXA screening results on women’s decisions for osteoporosis prevention. The study included 261 primarily Caucasian women ranging in age from 23 to 96 years ($M_{age} = 59$ years), many who reported having family history of osteoporosis (38%), or a medical condition related to osteoporosis (30%). Majority of women in the study were referred for DXA by their physician (90%). Seven months after screening, 95% of women reported discussing DXA results with their physician of whom 53% were told their BMD was below normal and 94% initiated some type of preventive measure. Those who reported below-normal BMD
were statistically significantly more likely to begin preventive health behaviours than women who reported normal results (56%, $p \leq 0.01$). Specifically, women reporting below-normal results were more likely to start calcium supplements (55% vs 17%, $p \leq 0.01$), increase calcium supplements (47% vs 19%, $p \leq 0.01$), increase consumption of milk or calcium-rich foods (59% vs 19%, $p \leq 0.01$) and start vitamin D supplements (35% vs 9%, $p \leq 0.01$) compared to women reporting normal results. Anastasopoulou and Rude (2002) also reported nine to 12 months after older adult women ($N = 238$) received DXA screening, 48% of women with osteoporosis and 33% with osteopenia increased their calcium intake, although it was unknown whether this included supplements and/or food intake. Notably, neither study evaluated health behaviours prior to DXA screening; therefore, actual change in behaviours was unknown. In addition, calcium and vitamin D intakes were based on self-report (e.g. “Did you increase calcium intake, yes or no?”).

Only three studies in the research literature were found to assess change in calcium intake after DXA screening. McLeod, McCann, Horvath, and Wactawski-Wende (2007) determined whether results of DXA screening influenced 923 postmenopausal Caucasian women’s decisions to initiate or change total calcium intake (diet and supplement). Participants were recruited from the community and were eligible if they had not received DXA screening before and were not taking osteoporosis drug treatment, other than HT. One year after DXA screening women were mailed a self-report follow-up questionnaire to determine change in dietary intake. Results showed 36% of women were newly diagnosed with osteoporosis, and 48% had osteopenia. Of those screened, 43% made a change in their calcium intake. Factors associated ($p < 0.05$) with increase in calcium intake included BMI, follow-up consultation with a HCP, and osteopenia or
osteoporosis diagnosis compared to normal T-score. Osteopenia ($OR = 2.37$, 95% CI [1.45, 3.89], $p = 0.001$) and osteoporosis ($OR = 3.86$, 95% CI [2.30, 6.46], $p < 0.001$) were strong independent predictors of women’s decisions to initiate or increase calcium intake. Although food frequency questionnaires were completed at baseline, they were not administered at follow-up, thus there was possible bias arising from self-reports of dietary and supplement calcium intake in follow-up questionnaires. In another study by Rohr, Clements, and Sarkar (2006), a follow-up telephone survey was completed by 234 postmenopausal women ($M_{age} = 74$ years) two years after participating in a community-based BMD screening program. Among women with normal BMD, there was a statistically significant increase in calcium supplement intake ($p = 0.002$) after screening (37% before vs 61.6% after). Women with low BMD (osteopenia or osteoporosis), were also found to have a statistically significant increase in calcium supplement intake (45.4% vs 78.5%; $p = 0.001$) after screening. It is important to note that in addition to screening, women received recommendations for calcium intake and were referred to their HCP for follow-up. Whether they took this step and whether they received recommendations from their HCP were not studied. Few studies evaluate men, with only one assessing change in calcium intake ($N = 196$, $M_{age} = 65.9$ years), showing those with osteopenia and osteoporosis increased total calcium intake six months post-screening (Doheny, et al., 2010). In summary, none of the studies reviewed evaluated the influence of DXA screening results on change in vitamin D intake, results were largely based on self-report or there was little detail on measurement method, and majority of studies were community-based (e.g., recruitment from churches, senior centres, etc.) and may not have captured samples representative of the population at risk for osteoporosis. Also, two of
the studies did not report whether DXA screening results were based on subjects’ first screening experience.

It is evident there is a need to determine the influence of DXA screening on change in dietary and supplemental calcium and vitamin D intake in adult men and women. Only three studies reported on change in calcium intake, with no assessment of vitamin D intake (Doheny, et al., 2010; McLeod, et al., 2007; Rohr, et al., 2006). Since vitamin D is essential for bone health when combined with calcium intake there is a need to evaluate initiation or increase of this vitamin in both men and women. In addition, none of the studies reviewed evaluated actual supplement intake (mg/day) and dietary intake via food diaries before and after screening, which would provide a more accurate understanding of change in calcium and vitamin D intake.

The factors associated with making a behaviour change are also important to assess. For example, whether an individual discusses the results of DXA screening with a HCP, whether the HCP makes a recommendation for health behaviour change, and whether the individual follows the recommendation, may largely influence men and women’s decisions to make a change. Only one study evaluated the independent influence of DXA screening results on health behaviour (calcium intake) change after adjusting for potentially confounding factors. Determining the odds ratio is important to identify the primary factors influencing health behaviour change, as it provides useful information to guide health promotion efforts (McLeod, et al., 2007).

2.5.2 Change in Physical Activity

Physical activity, particularly weight-bearing and strength training exercise, is important for the prevention and management of osteoporosis and related fracture;
however very few studies have evaluated change in physical activity and the influence of DXA screening results on men and women’s decisions to initiate or increase physical activity. Rubin and Cummings (1992) found that seven months after screening, women reporting below normal results were significantly more likely to start exercise compared to women reporting normal results (34% vs 15%, $p \leq 0.01$), although there was no baseline data for comparison prior to screening. Also, women were more likely to increase their current amount of exercise if they reported below normal screening results (43% vs 24%, $p \leq 0.01$). Similarly, Rohr et al. (2006) found nearly two years after screening, 39% of postmenopausal women with normal BMD, and 31% with low BMD reported an increase in exercise; however, there was no baseline data for comparison. As shown in both studies, the time lapse between screening and follow-up, whether seven months or two years, did not appear to affect women’s reported decisions to increase exercise.

Only one study involving men ($N = 196, M_{\text{age}} = 65.9$ years), assessed change in physical activity and used a validated measurement tool (the 39-item Yale Physical Activity Survey) (Doheny, et al., 2010). Results showed DXA results indicating osteopenia and osteoporosis did not influence walking behaviour. Limitations to this study and those previously described were primarily lack of assessment of actual change in physical activity with assessment largely based on self-report post-screening. More importantly, only one study discussed the use of a validated physical activity questionnaire. Assessing physical activity in older adults using a validated measurement tool is ideal to identify the type and amount of physical activity performed. Also, as previously discussed with regard to change in calcium and vitamin D intake, none of the
studies assessed factors associated with change in physical activity after screening. There is clearly a need to further evaluate older adult men and women’s decisions to start or increase physical activity after DXA screening. The type and amount of physical activity are important factors influencing bone maintenance, for example, weight-bearing exercise that is stopped or reduced during older adulthood will result in increased bone resorption. Unfortunately, the majority of older adults are not engaging in regular physical activity; however, DXA screening results may influence decisions to initiate or increase this health behaviour for prevention and management of osteoporosis.

2.5.3 Initiation of Drug Treatment

Studies have suggested that HCPs recommend and women initiate osteoporosis drug treatment more often when DXA screening results indicate increased risk of fracture (Brennan, et al., 2004; Cranney, Tsang, & Leslie, 2009; Fitt, et al., 2001; Rubin & Cummings, 1992). However, most of these studies have been limited to retrospective design and assess women only (Brennan, et al., 2004; Cranney, et al., 2009; Rubin & Cummings, 1992). While osteoporosis was historically considered a disease primarily affecting women, in the past decade it has now become evident that men are also largely at risk of osteoporosis and related fracture. Therefore, there is a need to assess the influence of DXA screening on older adult men’s decisions to initiate treatment for the disease.

Brennan, Wactawski-Wende, Crespo, and Dmochowski (2004) assessed factors associated with drug treatment initiation after community-based DXA screening among postmenopausal women who had never been screened. Of the 945 women who completed baseline questionnaires, osteoporosis was newly detected in 344 (36.4%). One
year after screening, 250 (72.7%) women with osteoporosis discussed results with their HCP, and 56.0% of those initiated drug treatment. Factors associated with treatment initiation were lower T-score (osteopenia or osteoporosis), having a history of routine medical care, and college education, having a family income ≥ $50,000, and discussing screening results with a gynecologist as opposed to other physician specialty. A Canadian retrospective cohort study assessed factors associated with treatment initiation, specifically systemic estrogen, bisphosphonates, calcitonin, or raloxifene, after DXA screening in women 50 years of age (N = 8,689) and older who had not taken osteoporosis treatment in the year prior to DXA. During a 1-year follow-up, 44% of women were dispensed an osteoporosis drug treatment, of which 77.9% were non-estrogen medications. Prescription initiation increased significantly with decreasing BMD T-scores (p < 0.001), of which 41% were osteopenic and 78.5% were osteoporotic. BMD T-score level was a strong predictor of treatment initiation (OR = 4.33, 95% CI [4.03-4.64], p < 0.001), while age, body weight, and fracture history were not (Cranney, et al., 2009).

In the only prospective study by Fitt et al. (2001), 335 Canadian women over 50 years of age were referred for DXA screening at a primary care setting for the first time. Three months after screening and baseline data collection, 40.9% and 23.6% of women, respectively had osteopenia and osteoporosis. Prior to screening, 15.2% of women were receiving HT or bisphosphonate therapy, which increased to 63.3% after screening, yet one third of women with osteoporosis were not receiving any treatment at follow-up. This suggested that while DXA screening results influenced treatment initiation, discussing results with a HCP was a critical component in the decision to initiate treatment, as was
the importance of HCPs in facilitating an understanding of the results with their patient. Notably, factors independently associated with treatment initiation were similar to those found in previous studies discussed by Brennan et al. (2004) and Cranney et al. (2009) and included BMD result indicating osteoporosis, perception that results showed bone loss, and discussion of results with a HCP.

Several of the studies discussed in previous sections also evaluated women’s decisions to initiate drug treatment after DXA screening, but had mixed results. Anastasopoulou and Rude (2002) determined prior to screening, 45% of women were receiving some type of osteoporosis drug treatment. After follow-up (nine to 12 months), 37 (16%) began drug treatment: alendronate in 10%, estrogen in 3%, and calcitonin and raloxifene with 1% each. In those with osteoporosis (n = 58) and osteopenia (n = 113), 38% and 45% respectively, were already receiving therapy and this increased to 78% and 59% after DXA screening. Contrary to these results, a community-based study by Rohr et al. (2006) found that women with normal BMD and low BMD had no significant difference in use of alendronate, calcitonin, and SERMs before and after screening. A major reason may have been associated with HCP follow-up. Participants were responsible for making appointments to discuss their results with a HCP and it is likely that many of them did not take this step. The study by Brennan et al. (2004) was also community-based; however, results of DXA screening were mailed to participants’ chosen HCPs for review and thus likely influenced treatment initiation. It is of interest to prospectively study the effects of DXA screening results on drug treatment initiation in at-risk men and women attending a primary care setting.
At the time several of these studies were conducted, HT was still widely prescribed; therefore, further insight regarding current prescribed drug therapies is of interest (Anastasopoulou & Rude, 2002; Brennan, et al., 2004; Cranney, et al., 2009; Fitt, et al., 2001; Rubin & Cummings, 1992). Rubin and Cummings (1992) found that women reporting below normal results were nearly five times more likely to be taking HT than women reporting normal results. After multivariate adjustment for confounding factors including education, family history of osteoporosis, previous hip or vertebral fracture, presence of a medical condition related to osteoporosis and perception of risk for fracture prior to DXA, below normal screening result was a strong independent predictor of women’s decisions to start HT. It was not determined whether HCPs made particular recommendations to influence such changes.

An important component of study design in health behaviour change research is the duration of follow-up (R. E. Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004). The previous sections reviewing studies of calcium and vitamin D intake, physical activity, and drug treatment initiation after DXA screening varied in duration of follow-up from three months to two years with the majority ranging between six months to one year. A three month follow-up may not be adequate duration to assess change in osteoporosis-related health behaviours, particularly with regard to drug treatment that requires a HCP consultation and recommendation (Elliot-Gibson, Bogoch, Jamal, & Beaton, 2004). Understanding long-term effects of DXA screening results on health behaviour change is important to determine the effectiveness of screening. Assessing outcomes at six months or more provides greater insight to sustainability of behaviour change for prevention or management of osteoporosis.
2.6 Osteoporosis Education and Theoretical Framework

Much of the burden of osteoporosis may be avoided if preventive health behaviours are performed as early as possible to ensure maintenance of BMD, and reduced risk of fracture. DXA screening may be the first step in improving this likelihood; however, there is also a traditional lack of knowledge and awareness about these preventive health behaviours among older men and women. Combined with DXA screening, increased knowledge and awareness about osteoporosis can help older adults make informed decisions about health behaviours for the prevention and management of the disease beyond that of DXA screening alone. Thus, there is a crucial need to address primary prevention of osteoporosis as it relates to health promotion of modifiable health behaviours in this population. The long-term result may lead to less treatment, reduced fracture risk, and ultimately a reduction in the financial burden on Canada’s health care system.

2.6.1 Theoretical Framework: The Revised Health Belief Model (RHBM) of Behavioural Change

There are many theories that can be used to explain and evaluate the structural and psychological determinants of health behaviour and act as a guiding framework for health behaviour education interventions. Rosenstock’s Health Belief Model (HBM) is one of the most widely used psychosocial frameworks in health behaviour research and practice (Painter, Borba, Hynes, Mays, & Glanz, 2008; I. Rosenstock, 1966). It has been used across the health continuum of care, including primary, secondary, and tertiary disease prevention (Janz & Becker, 1984). With regard to osteoporosis, the HBM is the
most widely applied conceptual framework for evaluating osteoporosis health beliefs and their relationship to osteoporosis-related health behaviours (McLeod & Johnson, 2011).

The HBM suggests that an individual’s health beliefs are directly associated with the likelihood of participating in health behaviours, and that personal characteristics and experiences may modify these health beliefs, thus indirectly influencing health behaviour. Although the HBM was initially developed to explain preventive health behaviour, it can also be applied to the management of disease. The premise of the HBM is that individuals who perceive a threat from a disease and perceive greater benefits than barriers towards taking preventive action against the disease, will be more likely to engage in preventive health behaviour. Specifically, an individual’s actions to prevent or manage disease depend on the following constructs (as they relate to osteoporosis) (Figure 3):

a) Perceived susceptibility: beliefs about the risks or chances of being diagnosed with osteoporosis.

b) Perceived seriousness: belief about the seriousness of osteoporosis and that if left un-managed, it would have serious consequences. Perceived susceptibility and perceived seriousness combine to constitute perceived threat.

c) Perceived benefits: beliefs about the effectiveness of taking action to reduce risk or seriousness (e.g., calcium and vitamin D intake).

d) Perceived barriers: beliefs about the physical or psychological costs of taking action. If an individual perceives fewer barriers and greater benefits to taking action, then he/she is more likely to engage in the health behaviour to reduce risk.
e) Cues to action: including events or people that motivate individuals to take action (e.g., DXA screening or recommendations from a HCP).

f) Self-efficacy: belief in one’s ability to carry out behaviours and overcome barriers necessary to have the desired outcome, as derived from Bandura’s social cognitive theory (Bandura, 1977).

Self-efficacy was later introduced to the HBM with the intent to better predict factors associated with changing health behaviours. This created a single model now known as the Revised Health Belief Model (RHBM) (I. Rosenstock, et al., 1988). Notably, modifying factors such as demographics, socio-psychological variables, and structural variables may also influence beliefs, and thus indirectly influence health behaviours (Glanz, Rimer, & Viswanath, 2008).
Figure 3. Adaptation of the Revised Health Belief Model constructs and linkages for taking vitamin D supplements.
Since its development, a wide diversity of populations, health conditions, and health behaviours have been measured using the HBM. A meta-analysis of 46 studies was the first to summarize evidence supporting the HBM and found perceived susceptibility, seriousness, benefits, and barriers were significantly associated with the health behaviours studied (Janz & Becker, 1984). The most recent meta-analysis by Harrison, Mullen, and Green (1992) determined the relationship between the HBM constructs and health behaviour of 16 studies. All studies included in the review had to measure four HBM constructs (susceptibility, seriousness, benefits, and barriers), a behavioural dependent variable, and measures of reliability. Results of weighted mean effect sizes showed susceptibility, seriousness, barriers, and benefits were significant predictors of health behaviours. However, less than 10% of the total variance could be accounted for by any of the HBM constructs (i.e., effect sizes were small). It is important to note the same underlying construct may not always be measured in every study. Construct definitions must be consistent with the original HBM or RHBM theory and measures must be specific to the health behaviour and population being addressed (Glanz, et al., 2008). For example, barriers to osteoporosis screening may be different from barriers to colonoscopy.

Cues to action have not been systematically studied with major reasons being the absence of clear definitions for this concept or specific tools to measure the construct. Cues to action may include a wide variety of strategies such as recommendations from a HCP, DXA screening, or post card reminders. As previously discussed, studies have shown that HCP recommendations and DXA screening are effective in the context of
osteoporosis drug treatment initiation and changes in calcium intake (Brennan, et al., 2004; McLeod, et al., 2007).

2.6.2 Measurement of the Revised Health Belief Model Constructs

Modified questionnaires to measure RHBM constructs have been developed and applied in both descriptive and intervention research, including assessments of osteoporosis beliefs and behaviours. Testing reliability and validity of these questionnaires prior to research is essential to reduce error, especially when study populations being assessed are different from those used in the development studies.

Kim, Horan, Gendler, and Patel (1991) developed the Osteoporosis Health Belief Scale (OHBS) to evaluate health beliefs related to osteoporosis, and to determine the relationship between health beliefs and osteoporosis preventive health behaviours including calcium intake and exercise. The OHBS is a 42-item questionnaire based on the HBM constructs and was developed and validated in 201 women ages 35 to 95 years. The 42 items are separated into seven subscales: perceived susceptibility to osteoporosis, perceived seriousness of osteoporosis, general health motivation, benefits and barriers to calcium intake, and benefits and barriers to exercise. Cues to action were not included in the OHBS as it is a difficult construct to translate into a clearly defined measure in order to have theoretical coherence. Each item is rated using a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). The possible range of scores for each subscale is 6 to 30 with a possible total score range of 42 to 210. Cronbach’s alpha for both subscales ranged from .61 to .80. While studies have shown the OHBS is a promising tool for measuring health beliefs, it has not undergone extensive scrutiny particularly with regard to its factor structure and reliability in different populations (Johnson, McLeod, Kennedy, & McLeod, 2010).
2008). To date, the majority of studies published using the OHBS evaluate osteoporosis health beliefs in women; few studies have evaluated health beliefs in men.

While the OHBS does not measure self-efficacy, Horan, Kim, Gendler, Froman, and Patel (1998) later developed and evaluated the Osteoporosis Self-Efficacy Scale (OSES) as a measure of self-efficacy for behaviours related to exercise and calcium intake. The OSES (12-item and 21-item versions) was developed and validated in the same study sample as the OHBS. Each version has two subscales: the Osteoporosis Self-Efficacy (OSE)-Exercise scale (6 or 10 items) and the Osteoporosis Self-Efficacy (OSE)-Calcium scale (6 or 11 items). A 100 mm visual analog scale is used to rate confidence in performing exercise and calcium intake (0 = not at all confident, 100 = very confident). Scores range from 0 to 100 for each subscale, with a possible total range of 0 to 200 for the OSES. Results showed the OSE-Exercise and OSE-Calcium scales had internal consistency estimates of .90 for both scales of the 12-item version, and .94 and .93 respectively for the 21-item version.

2.6.3 Osteoporosis Health Beliefs in Men and Women

Osteoporosis health beliefs in men and women may impact decisions to change preventive health behaviours. Such beliefs may also provide useful information for targeting certain constructs of health belief perceptions of a population when developing osteoporosis education interventions. A recent systematic review of common osteoporosis health beliefs, as measured by the OHBS and OSES, in adult men and women from descriptive studies showed individuals generally have low to moderately high perceived susceptibility, moderate to high perceived seriousness, health motivation, and self-efficacy of calcium intake and exercise, high perceived benefits of calcium
intake and exercise, and low to moderate barriers to calcium intake and exercise (McLeod & Johnson, 2011). While these studies have shown the OHBS is a promising tool for measuring health beliefs, there remains a great deal of uncertainty regarding the generalizability of these measurement tools across populations, including various ethnicities, males, and age groups.

There is limited research evaluating osteoporosis health beliefs and behaviours in men as it is only in the past decade that research has drawn attention to osteoporosis prevalence in men. This may also explain the differences in health beliefs between men and women. Comparing gender groups, results of the systematic review found, overall, women are significantly more likely to perceive themselves as susceptible to osteoporosis, and perceive greater benefits to calcium intake and barriers to exercise compared to men. They also perceive significantly fewer barriers to calcium intake, but perceived more barriers to exercise and lacked health motivation and confidence to exercise compared to men (Doheny, Sedlak, Estok, & Zeller, 2007; Johnson, et al., 2008; McLeod & Johnson, 2011). For example, Johnson, et al. (2008) found that men over 50 years of age had significantly lower perceived susceptibility scores compared to women over 50 years of age, supporting the notion that osteoporosis is perceived as a disease primarily affecting women; therefore, women may be more aware and knowledgeable than men about osteoporosis and related preventive behaviours. These results also suggest men continue to be unaware of the importance of osteoporosis-related health behaviours for prevention and management of the disease; despite being more confident in their ability to engage in exercise.
Another study determined whether there is a difference in osteoporosis-related health beliefs between men 50 years of age and older \((n = 226)\) and women 50 to 65 years of age \((n = 218)\) (Doheny, et al., 2007). Results showed men did not perceive themselves to be susceptible to osteoporosis and did not perceive osteoporosis to be serious compared to women who scored significantly higher on these constructs. In addition, when compared to women, men scored significantly lower on benefits of calcium intake and barriers to exercise. However, when compared to women, men scored significantly higher on barriers to calcium intake and health motivation. It is of interest to note that after DXA screening, 50.3% of men were diagnosed with either osteopenia or osteoporosis. Sedlak, Doheny, and Estok (2000) conducted a descriptive study to determine health beliefs about osteoporosis and confidence in performing osteoporosis-related health behaviours in 138 men over 65 years of age. Similar to results of other studies, men did not perceive themselves as susceptible to developing osteoporosis. They also had moderately-high confidence in performing exercise or calcium intake for osteoporosis prevention. However, only one third reported engaging in weight-bearing exercise twice a week and the average calcium intake was 542.57 mg/day, well below the recommended daily intake of 1,200 mg/day. Overall, these studies indicate the need for increased awareness of osteoporosis in men, specifically with regard to their perceived susceptibility and what they believe they can do to prevent or manage the disease.

2.6.4 Relationship between Osteoporosis Health Beliefs and Health Behaviour

Osteoporosis health beliefs in men and women may impact decisions to change preventive health behaviours. Studies in older adults have identified barriers as the most common health belief construct impacting osteoporosis-related health behaviours (Cline
Validation of the OHBS demonstrated greater health motivation and fewer perceived barriers to calcium intake and exercise as the most important constructs explaining exercise and calcium intake behaviours in older adults (Kim, et al., 1991). Women who perceived themselves as susceptible to osteoporosis and perceived many benefits and few barriers to calcium intake were more likely to use calcium and vitamin D supplements (Cline & Worley, 2006). These results are consistent with the general HBM literature findings wherein perceived barriers and susceptibility are the most significant constructs influencing health behaviours (Harrison, et al., 1992; Janz & Becker, 1984).

Since its development, several studies using the OSES have shown that self-efficacy of calcium intake and exercise are significantly related to calcium intake and exercise behaviour for osteoporosis prevention and management in women (Estok, Sedlak, Doheny, & Hall, 2007; Swaim, Barner, & Brown, 2008; Wallace, 2002). Most of these studies were cross-sectional surveys based on self-report. Thus, it is possible that women were already exercising and consuming calcium, which may have increased their confidence to perform these behaviours. No studies were found that evaluated self-efficacy and its relationship to osteoporosis preventive behaviours in men.

2.6.5 Osteoporosis Education Interventions

Health education is an area of research and practice devoted to health promotion. Simonds (1977, p. 588) defined health education as “bringing about behavioural changes in individuals, groups and larger populations from behaviours that are presumed to be detrimental to health, to behaviours that are conducive to present and future health”. Therefore, the overall goal of health education is to ensure individuals or groups have an
understanding of their current health status in order to make informed decisions and health behaviour changes for optimal health.

Current research suggests theoretically informed programs and interventions are more effective in changing health behaviour in research and practice than those developed without theoretical basis (Grol, Bosch, Hulscher, Eccles, & Wensing, 2007; Noar, Benac, & Harris, 2007; Noar & Zimmerman, 2005). Based on systematically reviewed research literature, perceived seriousness, susceptibility, benefits, barriers, and self-efficacy of calcium intake and exercise, are the most important osteoporosis health beliefs in older men and women for behaviour change (McLeod & Johnson, 2011). Thus, in order to strive for prevention or optimal management of osteoporosis, it is important to consider these health beliefs when planning education interventions. This would include educating individuals on the seriousness of the disease and its consequences, ensuring awareness of the potential deterrents to preventive behaviours, as well as the benefits of calcium and vitamin D intake, and physical activity. Additionally, providing individuals with information and guidance needed to perform these health behaviours, verbal reinforcement, and/or demonstrating the desired behaviour, would foster self-efficacy of calcium intake and physical activity. Taking RHBM constructs into consideration when planning osteoporosis education interventions will help guide decisions for design, procedures, and measurement indicators and ultimately help effectively address the factors that lead to positive health behaviour, therein improving prevention and management of the disease. Such quality improvements in education interventions would have long-term cost-saving benefits for the health care system when compared to the costs associated with implementing health promotion efforts based on intuition and
personal judgement with little outcome effect, in addition to the costs of treating and caring for individuals who have already suffered a fracture.

Osteoporosis education intervention studies using theory, and in particular, the RHBM as a guiding framework, are limited and vary in study population and design, method of education intervention, and length of follow-up (Babatunde, et al., 2011; Sedlak, et al., 2000; Tussing & Chapman-Novakofski, 2005). For example, an eight-week osteoporosis education program based on the RHBM using short lectures, hands-on activities to increase self-efficacy, and handouts to reinforce behaviours related to calcium intake resulted in significantly increased perceived susceptibility to osteoporosis ($p < 0.001$), increased perceived benefits to increasing calcium intake ($p < 0.001$), and increased self-efficacy related to calcium intake ($p \leq 0.003$) in women ($N = 42$, $M_{age} = 48$ years). Calcium intake also significantly increased ($p < 0.001$) from 644 mg/day to 821 mg/day; however, the study did not determine which health belief constructs were related to this change (Tussing & Chapman-Novakofski, 2005).

A recent experimental study showed the delivery of six weekly, RHBM-based group education sessions improved dietary calcium intake in African-American men ($n = 11$) and women ($n = 99$) over 50 years of age. However, other health behaviour outcomes were not assessed and it was unknown whether men and women had ever undergone DXA screening (Babatunde, et al., 2011). In contrast, Sedlak, Doheny, and Jones (2000) found no significant change in calcium intake and weight-bearing exercise after RHBM-based education focusing on susceptibility to osteoporosis and barriers to osteoporosis-related health behaviours in women ages 22 to 83 years. This was true, regardless of the length and method of education presentation, including a three week, three hour, and 45
minute program. Notably, non-randomized, convenience samples of women ranging in age from young to older adults were examined. However, the authors reported anecdotal data from the participants regarding their perceived susceptibility to developing osteoporosis, perceived benefits of calcium intake, and health motivation. For example: “Knowing more about osteoporosis is really motivating me to go and do something, especially at my age.” “I wish I had been drinking more milk while growing up.” “I never thought osteoporosis was a problem since I walk everyday and I have ‘strong bones’ but since my mother just fell and broke her hip I may have a problem too.” In addition to there being little difference in health beliefs after the programs, health behaviours related to calcium intake and weight-bearing exercise did not significantly change three weeks after each educational program. When using RHBM-based osteoporosis interventions, one generalized education program may not be appropriate for the specific needs of every individual. This may explain why there were no changes in behaviours in this study population as education groups included both younger and older women.

While studies aside from those discussed have evaluated the usefulness of osteoporosis education on health behaviour change, the methods do not specify whether educational interventions were based on a theoretical framework or they do not provide enough detail about the intervention. RHBM-based education intervention studies that are longitudinal, employ RCTs, and particularly with a usual care group for comparison, examine a change or initiation of an osteoporosis-related health behaviour as the outcome, evaluate at-risk men and postmenopausal women, and have larger sample sizes would provide greater insight to their usefulness.
2.6.6 Influence of Osteoporosis Education Combined with DXA Screening on Health Behaviours

Previous studies have shown that changes in health behaviours after DXA screening or after osteoporosis education are apparent (Babatunde, et al., 2011; Brennan, et al., 2004; McLeod, et al., 2007). However, the influence of DXA screening combined with theory-informed osteoporosis education may lead to an increased likelihood of health behaviour change in at-risk men and women beyond that of DXA screening or education intervention alone. Of interest, is the variability in health behaviour decision-making that is accounted for by DXA screening alone compared to DXA screening plus theory-informed osteoporosis education.

Only one study was found that used a theoretical framework for the education intervention combined with DXA screening on health behaviour outcomes. Sedlak, Doheny, Estok, and Zeller (2005) used tailored or personalized interventions, which have been shown to be more effective than general theoretically based education sessions. All participants (postmenopausal women, age range 50 to 65 years) underwent DXA screening for the first time, with those in the intervention group also receiving tailored interventions customized to their diagnostic screening results and behavioural and motivational characteristics based on RHBM constructs. Six months after the intervention, women in the tailored group ($n = 23$) perceived significantly more barriers to calcium intake ($p < 0.03$) and exercise ($p < 0.03$) than those in the non-tailored group ($n = 101$) who only received osteoporosis screening results. No significant differences were found for the other health belief constructs. Both the tailored and non-tailored intervention groups significantly increased their calcium intake ($p < 0.01$ and $p < 0.01$, p
respectively) and there was no significant difference between groups. Weight-bearing exercise behaviours significantly decreased in the tailored intervention group and there was small, but non-significant increase in the non-tailored group. These findings suggest that osteoporosis screening alone may be more effective in changing health beliefs and behaviours than combined screening and osteoporosis education. However, the unequal sample sizes, and lack of validated instruments used to determine calcium intake and exercise were major limitations in this study.

Several other studies have determined the effects of DXA screening and non-theoretical osteoporosis education on postmenopausal women’s decisions to change health behaviors associated with osteoporosis 12 months later (Marci, Wiechnicki, & Greenspan, 2000; Papaioannou, et al., 1998). A study involving 701 primarily Caucasian women referred to an osteoporosis prevention program found that after DXA screening and an education video, women with moderate or severe low BMD were more likely to report starting or increasing calcium supplement use ($p < 0.01$), increasing dietary calcium ($p < 0.001$), starting or increasing weight-bearing exercise ($p < 0.01$), and starting HT ($p < 0.001$) compared to those with normal results (Marci, et al., 2000). Results did not indicate whether women received recommendation from their HCP. Also, since this was not an intervention study, the influence of DXA screening alone or combined with the education video on health behaviours was not compared. Papaioannou et al. (1998) also examined women’s decisions to start drug treatment after DXA screening and osteoporosis education. All women ($N = 37$) underwent DXA screening and received an education kit which included a video tape and workbook describing consequences of osteoporosis, effect of HT, and alternative methods for prevention. After
screening and education six (17%, \( p = 0.03 \)) women began HT and seven (20%, \( p = 0.02 \)) began taking bisphosphonates compared to baseline when no women were receiving treatment. There were no significant differences between BMD risk level and HT use or calcium intake; however, more women with low BMD were taking bisphosphonates compared to those with normal BMD (37% vs 0%, \( p < 0.01 \)). This study was limited in that the study sample was very small and did not include other outcome measures such as exercise and vitamin D intake. Other limitations were similar to those in the study by Marci et al. (2000) and neither of the studies evaluated men.

Similar to the study by Papaioannou et al. (1998) an RCT assessed the influence of DXA screening on HT initiation in 140 postmenopausal women (Silverman, Greenwald, Klein, & Drinkwater, 1997). Notably, HT use is no longer recommended as treatment for osteoporosis, although results may provide insight to the influence of screening and education on other drug treatments initiated. In this study the control group (\( n = 43 \)) received an educational booklet from the National Osteoporosis Foundation that discussed the benefits and risks to HT use, a prescription for HT, and a voucher for a DXA screening one year later. The experimental group (\( n = 97 \)) received the same educational booklet and HT prescription, as well as DXA screening at baseline. Women in the experimental group were significantly more likely to initiate HT (63%) than those in the control group, regardless of T-score (20%, \( p < 0.01 \)).

The only study assessing health behaviours after DXA screening and general education in men has been conducted; however, the study was not a RCT and change in behaviours was not determined (Patel, et al., 2003). Six months after screening, a questionnaire was administered to 102 primarily Caucasian men ranging in age from 48
to 84 years ($M_{age} = 68.7$ years). Men were classified as normal (30%), osteopenic (38%), or osteoporotic (31%). Based on self-report, initiation of calcium ($p < 0.05$) and vitamin D supplements ($p < 0.05$) was significantly more common in men with osteoporosis compared to those with osteopenia or normal BMD. Although, in men with osteopenia and normal BMD, 64% and 59% respectively initiated calcium and vitamin D supplementation after screening. There was no significant difference between BMD risk level and men’s decisions to start or increase exercise. Of those with osteoporosis, 34% started or increased exercise, as did 39% of those with osteopenia or normal BMD. Notably, the majority of men were recruited from a study of prostate cancer of which 67% were diagnosed with the disease, while only 33% were considered healthy. This may have affected men’s decisions to start or increase exercise. In addition, results showed men with osteoporosis were significantly afraid of falling ($p < 0.05$) compared to those with osteopenia or normal BMD; therefore, they may have been more reluctant to start or increase exercise. Initiation of bisphosphonate treatment in men was significantly more common in those with osteoporosis (41%, $p < 0.01$) compared to those with osteopenia (13%) or normal BMD (3%). While treatment initiation was likely attributable to HCP recommendation, the study did not assess confounding factors.

It is evident that well-designed, RCTs assessing the influence of DXA screening alone or combined with theory-informed osteoporosis education on health behaviours are lacking. Only one study discussed the use of a theoretically based education program; however, its content was not clearly defined, similar to the studies using non-theoretically based osteoporosis education. Whether the use of a theory-based osteoporosis education program influences health behaviour more than a general program is unclear, as is the
best method for administering the education to increase awareness and influence behaviour change (e.g., video, printed material). In addition to the few studies evaluating postmenopausal women’s decisions, to our knowledge, no studies examining the influence of theory-informed education and DXA screening have been conducted in men. From a practical, public health perspective theory-informed osteoporosis education interventions would target at-risk men and women, increase awareness about the disease and target key RHBM constructs for behaviour change. When combined with DXA screening results, which have been shown to influence health behaviour change, this primary and secondary prevention focus may have potential long-term cost-saving benefits for the health care system when compared to the costs of treating and caring for individuals who have already developed osteoporosis or experienced osteoporotic fracture.
CHAPTER 3: OBJECTIVES

This chapter describes the research objectives, specific aims, and hypotheses for Study 1, Study 2, and Study 3.

3.1 Study Objectives and Hypotheses

The study focused on two areas related to prevention and management of the osteoporosis: 1) Identifying, evaluating, and comparing the accuracy of risk assessment screening tools to the gold standard DXA, and 2) Understanding the care gap as it relates to osteoporosis education coupled with diagnostic screening on health behaviour change (calcium and vitamin D intake, physical activity, and drug treatment initiation) among those at risk. Specifically, study results attempted to provide insight on the following questions:

- What percentage of those screened are newly diagnosed with osteoporosis, osteopenia, or normal BMD?
- Do patient characteristics vary as defined by gender and BMD?
- Of the common validated clinical risk factor assessment tools, which has demonstrated the best discriminative performance?
- How do QUS and OST compare to DXA in terms of diagnostic accuracy? Can they be used as pre-screening tools?
- What percentage of men and women discuss their BMD screening results with their HCP? Of those, what percentage receive a recommendation to start or increase calcium and vitamin D intake, physical activity, and/or drug treatment initiation? Do men and women comply with these recommendations?
• What factors, including DXA screening results and theory-based osteoporosis education, influence health behaviour change in men and women?
• What are the implications of these research findings to improve the osteoporosis care gap?

3.1.1 Study 1 Objective

The objective of the first study was to conduct a systematic review to identify common validated clinical risk factor assessment tools in predicting low BMD in postmenopausal women.

Specific Aims:

1) Compare the performance of common clinical risk factor assessment tools.

2) Determine which assessment tool has demonstrated the best discriminative performance. Results of this aim were used to inform Study 2 objectives.

It was hypothesized the OST would be the most extensively validated assessment tool and demonstrate better discriminative performance in identifying women with low BMD by DXA with its use of only two risk factors (age and body weight) in its algorithm.

3.1.2 Study 2 Objective

The objective of the second study was to evaluate the discriminatory ability of calcaneal QUS and OST compared to the reference diagnostic “gold standard”, DXA, for identifying osteoporosis in men and women 50 years of age and older.

Specific Aims:

1) Examine the relationship between calcaneal QUS, OST and the diagnostic “gold standard”, DXA.
2) Evaluate the diagnostic accuracy of calcaneal QUS and OST in identifying men and women 50 years of age and older with osteoporosis as defined by DXA.

3) A further aim of the study was to determine optimal cut-offs for QUS and OST to identify osteoporosis risk in this population.

It was hypothesized that both QUS and the OST would be efficacious pre-screening tools for identifying men and women at high risk of low BMD and that both QUS and the OST will significantly correlate with DXA, with the QUS having a larger correlation to DXA than the OST.

3.1.3 Study 3 Objective

The objective of study 3 was to determine the influence of DXA screening results combined with theory-based osteoporosis education on men and women’s decisions to start or increase health behaviours for prevention and/or management of the disease versus usual care (DXA screening alone). Change in calcium and vitamin D intake, physical activity, and osteoporosis drug treatment were the main outcomes of interest.

Specific Aims:

1) Evaluate men and women’s decisions to start or increase calcium intake (dietary and supplement) and the factors influencing change, specifically DXA screening results and theory-based osteoporosis education.

2) Assess men and women’s decisions to start or increase vitamin D intake (dietary and supplement) and the factors influencing change, specifically DXA screening results and theory-based osteoporosis education.
3) Determine men and women’s decisions to start or increase physical activity and the factors associated with change, specifically DXA screening results and theory-based osteoporosis education.

4) Investigate men and women’s decisions to initiate osteoporosis drug treatment and the factors associated with initiation, specifically the influence of DXA screening results and theory-based osteoporosis education intervention.

It was hypothesized that DXA screening results indicating osteoporosis or osteopenia will be more likely to influence health behaviour changes in men and women than those with normal BMD. It was also hypothesized that men and women receiving the intervention (osteoporosis education) would be more likely to change their health behaviours compared to those only receiving DXA screening. Furthermore, receiving the education and DXA results indicating osteoporosis or osteopenia would be more likely to change health behaviours compared to those with normal BMD and usual care (DXA screening) alone. We anticipated these factors would be independently associated with change in health behaviours after adjusting for confounding factors.

3.2 Structure of Thesis Results

The following three Chapters are presented as long papers in manuscript format presenting the results of the Study 1 (Chapter 4), Study 2 (Chapter 5), and Study 3 (Chapter 6). Each chapter is written as a complete and separate study beginning with an introduction, followed by methods including study design and setting, participants, procedure, study measures, and ethical considerations where applicable. Results with respective tables and figures, discussion, and conclusion will complete each Chapter. Multiple appendices supplement the studies providing additional details related to the
study methods, measures, and data analysis plans including variable definitions. The final chapter, Chapter 7, summarizes overall conclusions of the thesis research, implications for osteoporosis prevention and management, and directions for future research.
4.1 Introduction

Osteoporosis is a progressive, systemic skeletal disorder characterized by decreased bone strength with a consequent increase in bone fragility and risk of fracture, particularly fractures of hip, wrist and spine (Papaioannou, et al., 2010). Although osteoporosis may occur at any age, prevalence increases markedly with age and is expected to rise considerably due to unprecedented population aging (Greenspan, et al., 1997). In particular, postmenopausal women are at greater risk of osteoporosis due to accelerated bone loss (2% to 5% per year), largely as result of reduced estrogen production (Hannan, et al., 2000). Currently, over 2 million Canadians have osteoporosis, of which one in four are women and one in eight are men over 50 years of age.

DXA is considered the gold standard screening method for diagnosing osteoporosis or low BMD (Papaioannou, et al., 2010). However, screening all Canadians over 50 years of age is virtually impossible given the limited availability and high cost of DXA machines, and trained technicians required for machine operation. Based on Canadian clinical practice guidelines, men and women over 50 years of age should be routinely screened for clinical risk factors for osteoporosis and related fracture to identify those at high risk of low BMD who should subsequently undergo DXA screening (Papaioannou, et al., 2010). The guidelines also recommend all men and women 65 years of age and older undergo DXA screening regardless of additional risk factors (Papaioannou, et al., 2010). While it is ideal to measure BMD based on these clinical guidelines, it is not practical from a public health perspective and studies show despite practice guidelines, majority of at-risk individuals are not being screened (Jiwa, et al., 2008).
There is a need to improve screening efficiency and usefulness. A potentially worthwhile solution involves identifying at-risk men and women with low BMD, who will subsequently be suitable candidates for DXA screening, based on a simple evaluation of clinical risk factors associated with osteoporosis. Several clinical risk factor assessment tools using various algorithms have been developed and validated for their efficacy in detecting postmenopausal women at increased risk of low BMD (Cadarette, et al., 2000; Koh, et al., 2001; Lydick, et al., 1998; Michaelsson, et al., 1996; Sedrine, et al., 2002; Weinstein & Ullery, 2000). These tools have potential benefits for HCPs to not only increase awareness of osteoporosis and low BMD, but also assist in their decision making of patients who would benefit most from DXA screening. Consequently, this may increase DXA screening efficiency and cost-effectiveness by reducing the number of women referred who are otherwise healthy. The purpose of this systematic review was to identify validated clinical risk factor assessment tools for postmenopausal women, and assess the discriminative performance of these tools in determining postmenopausal women who are likely to have low BMD.

4.2 Methods

A computerized search of articles published from 1990 until January 2008 was performed in three databases: PubMed/Medline, PsychInfo, and the Cochrane Library. A literature search prior to 1990 was not warranted as osteoporosis risk factor assessment tools were developed after this time. The following keywords and possible combinations were used to identify primary articles (synonyms are shown in brackets): osteoporosis screening tool (assessment, testing, instrument, index), clinical assessment tool (screening, risk, index, instrument), postmenopausal women, validation (performance,
evaluation, comparison), and osteoporosis (low bone mineral density, bone mineral density). Men were excluded from the review as few studies have validated osteoporosis clinical risk factor assessment tools in this population; therefore, limiting a comprehensive review.

Titles and abstracts of all identified citations from the literature search were screened and the reference lists of all primary articles were examined to identify additional relevant publications until no new material meeting the search criteria was found. Based on this search, 46 articles were recognized as potentially suitable for inclusion. All citations were exported to reference software, EndNote X for Windows 7, for reference management. Full-text articles for the citations were retrieved and two reviewers independently evaluated the introduction, methodology, results, and discussion sections for quality and relevance based on the following inclusion criteria: (a) Population: includes postmenopausal Caucasian women; (b) Intervention: validated osteoporosis risk factor assessment tool; (c) Outcome measurement: low BMD based on corresponding cut-off values created in development cohort of the screening tool. Articles were also limited to English-language and full articles published in peer-reviewed journals. Of the 46 articles selected, 24 were excluded as summarized in Figure 1. The level of agreement between the two independent reviewers was 82% (18 of 22 articles selected). In the case of disagreement regarding selection of articles meeting defined inclusion criteria, the two reviewers resolved inconsistencies in a consensus meeting. A decision was made to include 22 primary articles, representing 33,628 women in the final set of articles for review.
Data abstraction and synthesis of the final set of articles selected in the review was based on the research question and included evaluation of clinical risk factor assessment tools, population, and results, specifically sensitivity, specificity, and AUC of the assessment tools. Using a standardized table, data were extracted based on the risk factor assessment tool (target population, risk factors used, cut-off values, and algorithm), population characteristics (sample size and age), and results (sensitivity, specificity, and AUC) were entered for further synthesis. The data were reviewed and differences in the assessment tools’ performance were noted.
Figure 4. Flowchart summarizing the systematic review search process and study identification.
4.3 Results

This study is the first systematic review of the performance of clinical risk factor screening tools for osteoporosis in postmenopausal women. Based on the inclusion and exclusion criteria, six risk factor assessment tools were identified. Characteristics of the assessment tools and their efficacy are shown in Table 1 and Table 2, respectively. The assessment tools included the Simple Calculated Osteoporosis Risk Estimation (SCORE), the Osteoporosis Risk Assessment Instrument (ORAI), the Osteoporosis Self-Assessment Tool (OST), the body weight criterion (BW), the Osteoporosis Index of Risk (OSIRIS), and Age, Body Size, No Estrogen (ABONE) (Cadarette, et al., 2000; Koh, et al., 2001; Lydick, et al., 1998; Michaelsson, et al., 1996; Sedrine, et al., 2002; Weinstein & Ullery, 2000). All of the assessment tools were developed, validated and used in community settings only. The algorithms for the assessment tools and their cut-off values are presented in Table 1. The assessment tools were developed using various BMD outcomes and sites as defined in Table 1. SCORE and ORAI used T-scores ≤ -2.0 to indicate high risk for osteoporosis or low BMD. The OST, BW, OSIRIS, and ABONE used T-scores ≤ -2.5 to define low BMD. Common sites for BMD assessment include the femoral neck, total hip, and lumbar spine. Several of the studies validated the assessment tools using different BMD outcomes and screening sites than those used in the original cohorts. Following the inclusion and exclusion protocol established for the review, only those studies that used the cut-off values determined in the development cohorts of each screening tool were selected and reviewed.
<table>
<thead>
<tr>
<th>Assessment tool</th>
<th>Target population</th>
<th>Cut-off value (development cohort)</th>
<th>Risk factors</th>
<th>Algorithm</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORE</td>
<td>Identify postmenopausal women likely to have femoral neck T-score ≤ -2.0</td>
<td>≥ 6</td>
<td>Age, body weight (lb), race, HT use, fracture history, history of rheumatoid arthritis</td>
<td>Points given for: race: +5 for race other than Black; +4 for rheumatoid arthritis; +4 for fracture (wrist, hip, rib) ≥ 45 years of age up to total sum of +12; +1 if never used HT; 3 x first digit of age, -1 x weight (lb) ÷ 10 and truncate to integer</td>
</tr>
<tr>
<td>ORAI</td>
<td>Identify postmenopausal women likely to have femoral neck or lumbar spine T-score ≤ -2.5</td>
<td>≥ 9</td>
<td>Age, body weight (kg), HT use</td>
<td>Points given for: age: +15 if ≥ 75, +9 if 65-74, +5 if 55 - 64, and 0 if 45-54 years; body weight: +9 if &lt; 60 kg, +3 if 60 - 70 kg, 0 if &gt; 70 kg; HT: +2 if not currently taking HT</td>
</tr>
<tr>
<td>OST&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Identify postmenopausal women likely to have femoral neck T-score ≤ -2.5</td>
<td>≤ -1</td>
<td>Age, body weight (kg)</td>
<td>Subtract age from body weight (kg), x 0.2, and truncate to an integer</td>
</tr>
<tr>
<td>BW</td>
<td>Identify postmenopausal women likely to have femoral neck T-score ≤ -2.5</td>
<td>Body weight &lt; 70 kg</td>
<td>Body weight (kg)</td>
<td>Body weight &lt; 70 kg</td>
</tr>
</tbody>
</table>
Table 3 (continued)

<table>
<thead>
<tr>
<th>Assessment tool</th>
<th>Target population</th>
<th>Cut-off value (development cohort)</th>
<th>Risk factors</th>
<th>Algorithm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OSIRIS</strong></td>
<td>Identify postmenopausal women likely to have total hip, femoral neck, or lumbar spine T-score $\leq -2.5$</td>
<td>+1</td>
<td>Age, body weight (kg), HT use, fracture history</td>
<td>Add the index weighted for each variable: body weight (kg) x 2 and remove last digit; age (yrs) x (-2) and remove last digit; +2 if current HT user; -2 if history of fracture</td>
</tr>
<tr>
<td><strong>ABONE</strong></td>
<td>Identify postmenopausal women likely to have femoral neck or spine T-score $\leq -2.0$</td>
<td>$\geq 2$</td>
<td>Age, body weight (kg), estrogen use</td>
<td>Points given for: age: +1 if &gt;65 yrs; body weight: +1 if &lt; 63.5 kg; estrogen use: +1 if never used oral contraceptives or estrogen for at least 6 months</td>
</tr>
</tbody>
</table>

*Nota.* SCORE = Simple Calculated Osteoporosis Risk Estimation; ORAI = Osteoporosis Risk Assessment Instrument; OST = Osteoporosis Self-Assessment Tool; BW = body weight criterion’ OSIRIS = Osteoporosis Index of Risk; ABONE = Age, Body Size, No Estrogen.

*Based on threshold scores developed and validated for Asian postmenopausal women. OST has since been validated in Caucasian women yielding a threshold score of < 2.*
The selected risk factor assessment tools have undergone thorough development and validation of their efficacy in identifying women likely to have low BMD. Validation of efficacy of the assessment tools includes the determination of sensitivity, specificity, and AUC. AUC is used to summarize the accuracy of a screening test (J. A. Hanley & McNeil, 1982). It represents sensitivity, the proportion of true positives among the total number of positive test results (i.e., correctly identifying individuals who have low BMD), and specificity, the proportion of true negatives among the total number of negative test results (i.e., correctly identifying individuals who do not have low BMD). Cut-off values for determining those who require DXA screening are typically chosen for optimal sensitivity and specificity. The AUC can also be used as a summary index of the test’s overall performance and may range from 0 to 1.00 whereby an AUC of at least 0.70 to 0.80 is necessary to regard a test as efficient (Streiner & Cairney, 2007). Table 2 summarizes the sensitivity, specificity, and AUC of each screening tool.

The SCORE was the first screening tool developed using six risk factors (age, body weight, race, hormone therapy use, fracture history, and history of rheumatoid arthritis) to predict DXA screening needs in postmenopausal women (Lydick, et al., 1998). It has since been widely evaluated. The SCORE was proven to be quite sensitive, ranging from 0.80 to 1.00 in the studies reviewed. However, SCORE results were not very specific, ranging from 0.07 to 0.63. This was true regardless of where BMD outcomes were assessed (e.g., femoral neck, lumbar spine) (Sedrine, et al., 2001). Cadarette et al. (2001) found that SCORE and ORAI had the best AUC performance at BMD T-scores ≤ -2.0 and ≤ -2.5; however, when restricted to T-scores ≤ -2.5 only, SCORE, ORAI, and BW were similar with AUC values of 0.80, 0.79, and 0.79,
respectively. When analysis was performed on study populations stratified by younger and older age groups, Sedrine et al. (2001) found the sensitivity of SCORE greatly improved in women 65 years of age and older but at the expense of a large decrease in specificity compared with women less than 65 years of age. Results among the same study population were concurred by Gourlay et al. (2005) who found no statistically significant difference in AUC values for women ages 45 to 65 years compared with women 65 years of age and older. However, Ungar et al. (2000) found a notable difference in AUC for younger postmenopausal women (0.73) compared with women in their 60’s (0.59).

The ORAI was developed within a population of postmenopausal Caucasian women from CaMos (Cadarette, et al., 2000). This simple tool uses three risk factors (age, body weight, and hormone therapy use) that can be easily determined in a clinical setting and has successfully identified over 90% of women at risk of low BMD in several studies (Cadarette, et al., 2000; Cadarette, et al., 2001; Cadarette, et al., 2004; Gourlay, et al., 2005; Gourlay, Powers, Lui, & Ensrud, 2008; Mauck, Cuddihy, Atkinson, & Melton, 2005). Despite postmenopausal age group, the AUC for ORAI were nearly identical to that of SCORE (Gourlay, et al., 2005). In another study of early postmenopausal women, keeping with the BMD outcomes of the original development cohort for ORAI, one in two women went undetected (sensitivity of 0.50); however, OST attained over 90% sensitivity indicating it may be more useful among younger postmenopausal women (Rud, et al., 2005).

The OST was first developed and tested in postmenopausal women from eight Asian countries but has since been applied and validated in Caucasian postmenopausal
women. The OST has achieved excellent performance with its use of only two risk factors (age and body weight) in the algorithm. The ability of OST to identify Caucasian postmenopausal women with femoral neck T-scores ≤-2.5 has been validated in several age groups with sensitivities ranging from 0.78 to 0.95, and specificities ranging from 0.37 to 0.71 indicating it is a useful tool in detecting those who have low BMD and is somewhat reliable in detecting those who do not (Brand, Lowe, & Hall, 2008; Cadarette, et al., 2004; Geusens, et al., 2002; Gourlay, et al., 2008; Richy, Gourlay, et al., 2004).

The BW criterion is the simplest of assessments for identifying women at high risk for osteoporosis (Michaelsson, et al., 1996). In the original cohort, body weight less than 70 kg identified postmenopausal women likely to have femoral neck T-scores ≤ -2.5 with a high sensitivity of 0.94 and a specificity of 0.36. This suggests women weighing over 70 kg are not in need of BMD screening. A sensitivity of 0.92 and specificity of 0.45 was determined when identifying osteopenia (BMD between 1.0 and 2.5 standard deviations below the optimal mean of healthy young women) of the total body in women of the same cohort.

The OSIRIS was developed using a population of postmenopausal Caucasian women from Belgium. It assesses age, body weight, hormone therapy use, and fracture history. A sensitivity of 0.79 and a specificity of 0.51 with an AUC of 0.71 were attained with an OSIRIS threshold score of +1 in the development cohort (Sedrine, et al., 2002). Richy et al. (2004) also validated OSIRIS in a much larger population of Caucasian Belgium women and found that OST performed much better (sensitivity of 0.86 and specificity of 0.40) than OSIRIS (sensitivity of 0.64 and specificity of 0.69) in identifying those with T-score ≤ -2.5 at the total hip, femoral neck, or lumbar spine.
Last, Weinstein and Ullery (2000) developed ABONE, a screening tool assessing age, body weight, and estrogen use, after obtaining DXA screening results from 1,610 postmenopausal women. ABONE was not validated in the development cohort; however, Cadarette et al. (2001) validated the screening tool and found a sensitivity of 0.83 and a specificity of 0.48 with an AUC of 0.72. Brand et al. (2008) also found ABONE had high specificity (0.84) but low sensitivity (0.56) indicating the assessment tool may be better in identifying individuals who do not have low BMD.
Table 4

Efficacy of Osteoporosis Clinical Risk Factor Assessment Tools

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Assessment tool</th>
<th>Study population (n) and age (M ± SD)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lydick et al. (1998) c, d</td>
<td>SCORE</td>
<td>1,279 (61.5 ± 9.6)</td>
<td>0.89</td>
<td>0.50</td>
<td>0.77</td>
</tr>
<tr>
<td>Lydick et al. (1998) c, d</td>
<td></td>
<td>208 (63.1 ± 9.5)</td>
<td>0.91</td>
<td>0.40</td>
<td>0.72</td>
</tr>
<tr>
<td>Von Muhlen et al. (1999) d</td>
<td></td>
<td>1,013 (72.5 ± 9.5)</td>
<td>0.98</td>
<td>0.13</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>511 (64.5 ± 6.0)</td>
<td>0.95</td>
<td>0.19</td>
<td>NR</td>
</tr>
<tr>
<td>Ungar et al. (2000) e</td>
<td></td>
<td>183 (age 50-59 years)</td>
<td>0.06</td>
<td>0.51</td>
<td>0.73</td>
</tr>
<tr>
<td></td>
<td></td>
<td>124 (age 60-70 years)</td>
<td>0.90</td>
<td>0.20</td>
<td>0.59</td>
</tr>
<tr>
<td>Cadarette et al. (2001) d</td>
<td></td>
<td>2,365 (66.4 ± 8.8)</td>
<td>0.98</td>
<td>0.21</td>
<td>0.77</td>
</tr>
<tr>
<td>Sedrine et al. (2001) d</td>
<td></td>
<td>4,035 (61.5 ± 8.8)</td>
<td>0.96</td>
<td>0.24</td>
<td>0.74</td>
</tr>
<tr>
<td>Gourlay et al. (2005) f</td>
<td></td>
<td>2,539 (56.0 ± 5.4)</td>
<td>NR</td>
<td>NR</td>
<td>0.76</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1,496 (70.7 ± 4.8)</td>
<td>NR</td>
<td>NR</td>
<td>0.75</td>
</tr>
<tr>
<td>Mauck et al. (2005) d</td>
<td></td>
<td>202 (69.2 ± 11.9)</td>
<td>1.00</td>
<td>0.29</td>
<td>0.85</td>
</tr>
<tr>
<td>Cass et al. (2006) g</td>
<td></td>
<td>59 (60.1 ± 9.2)a</td>
<td>0.80</td>
<td>0.63</td>
<td>0.68</td>
</tr>
<tr>
<td>Gourlay et al. (2008) d</td>
<td></td>
<td>7,235 (N/A)</td>
<td>0.99</td>
<td>0.07</td>
<td>0.73</td>
</tr>
<tr>
<td>Brand et al. (2008) f</td>
<td></td>
<td>127 (62)</td>
<td>1.00</td>
<td>0.10</td>
<td>0.73</td>
</tr>
<tr>
<td>Cadarette et al. (2000) b, e</td>
<td>ORAI</td>
<td>926 (62.8 ± 9.36)</td>
<td>0.90</td>
<td>0.45</td>
<td>0.79</td>
</tr>
<tr>
<td>Cadarette et al. (2000) c, e</td>
<td></td>
<td>450 (63.5 ± 10.0)</td>
<td>0.93</td>
<td>0.46</td>
<td>0.77</td>
</tr>
<tr>
<td>Cadarette et al. (2001) d</td>
<td></td>
<td>2,365 (66.4 ± 8.8)</td>
<td>0.94</td>
<td>0.32</td>
<td>0.76</td>
</tr>
<tr>
<td>Cadarette et al. (2004) g</td>
<td></td>
<td>644 (62.4 ± 11.2)</td>
<td>0.93</td>
<td>0.39</td>
<td>0.80</td>
</tr>
<tr>
<td>Richy et al. (2004) h</td>
<td></td>
<td>4,035 (61.5 ± 8.8)</td>
<td>0.77</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>D’Amelio et al. (2005) g</td>
<td></td>
<td>525 (N/A) a</td>
<td>NR</td>
<td>NR</td>
<td>0.32</td>
</tr>
<tr>
<td>Gourlay et al. (2005) f</td>
<td></td>
<td>2,539 (56.0 ± 5.4)</td>
<td>NR</td>
<td>NR</td>
<td>0.75</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1,496 (70.7 ± 4.8)</td>
<td>NR</td>
<td>NR</td>
<td>0.75</td>
</tr>
</tbody>
</table>
Table 4 (continued)

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Assessment tool</th>
<th>Study population ($n$) and age ($M \pm SD$)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geusens et al. (2002) (^\text{i, i})</td>
<td>OST</td>
<td>1,102 (61.3 ± 9.6)</td>
<td>0.88</td>
<td>0.52</td>
<td>NR</td>
</tr>
<tr>
<td>Cadarette et al. (2004) (^\text{g, i})</td>
<td>OST</td>
<td>644 (62.4 ± 11.2)</td>
<td>0.95</td>
<td>0.40</td>
<td>0.82</td>
</tr>
<tr>
<td>Richy et al. (2004) (^\text{f, i})</td>
<td>OST</td>
<td>4,035 (61.5 ± 8.8)</td>
<td>0.92</td>
<td>0.37</td>
<td>0.77</td>
</tr>
<tr>
<td>Richy et al. (2004) (^\text{h})</td>
<td>OST</td>
<td>4,035 (61.5 ± 8.8)</td>
<td>0.83</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>D’Amelio et al. (2005) (^\text{g})</td>
<td>OST</td>
<td>1,303 (67.1 ± 5.2)</td>
<td>0.80</td>
<td>0.40</td>
<td>0.63</td>
</tr>
<tr>
<td>Gourlay et al. (2005) (^\text{c, f})</td>
<td>OST</td>
<td>2,539 (56.0 ± 5.4)</td>
<td>0.88</td>
<td>0.48</td>
<td>0.70</td>
</tr>
<tr>
<td>Rud et al. (2005) (^\text{f, i})</td>
<td>OST</td>
<td>2,009 (50.5) (^\text{m})</td>
<td>0.92</td>
<td>0.71</td>
<td>NR</td>
</tr>
<tr>
<td>Gourlay et al. (2008) (^\text{f})</td>
<td>OST</td>
<td>7,617 (N/A) (^\text{a})</td>
<td>0.85</td>
<td>0.48</td>
<td>0.73</td>
</tr>
<tr>
<td>Brand et al. (2008) (^\text{f})</td>
<td>BW</td>
<td>127 (62) (^\text{m})</td>
<td>0.78</td>
<td>0.51</td>
<td>0.76</td>
</tr>
<tr>
<td>Michaelsson et al. (1996) (^\text{b, f})</td>
<td>BW</td>
<td>16 (N/A) (^\text{a})</td>
<td>0.94</td>
<td>0.36</td>
<td>NR</td>
</tr>
<tr>
<td>Cadarette et al. (2001) (^\text{f})</td>
<td>BW</td>
<td>2,365 (66.4 ± 8.8)</td>
<td>0.87</td>
<td>0.48</td>
<td>0.79</td>
</tr>
<tr>
<td>Cadarette et al. (2004) (^\text{g})</td>
<td>BW</td>
<td>644 (62.4 ± 11.2)</td>
<td>0.83</td>
<td>0.35</td>
<td>0.73</td>
</tr>
<tr>
<td>D’Amelio et al. (2005) (^\text{g})</td>
<td>BW</td>
<td>2,539 (56.0 ± 5.4)</td>
<td>0.80</td>
<td>0.48</td>
<td>0.70</td>
</tr>
<tr>
<td>Brand et al. (2008) (^\text{f})</td>
<td>BW</td>
<td>127 (62) (^\text{m})</td>
<td>0.72</td>
<td>0.53</td>
<td>0.63</td>
</tr>
</tbody>
</table>

\(^a\) Data not available
<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Assessment tool</th>
<th>Study population (n) and age (M ± SD)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geusens et al. (2001)</td>
<td>ABONE</td>
<td>2,365 (66.4 ± 8.8)</td>
<td>0.83</td>
<td>0.48</td>
<td>0.72</td>
</tr>
<tr>
<td>Brand et al. (2004)</td>
<td></td>
<td>127 (62)m</td>
<td>0.56</td>
<td>0.84</td>
<td>0.72</td>
</tr>
</tbody>
</table>

Note. NR = Not reported.

\(^a\) Mean age not provided, all women were postmenopausal. \(^b\) Development cohort. \(^c\) Validation cohort. \(^d\) Identify postmenopausal women likely to have femoral neck T-score ≤ -2.0. \(^e\) Identify postmenopausal women likely to have femoral neck or lumbar spine T-score ≤ -2.0. \(^f\) Identify postmenopausal women likely to have femoral neck T-score ≤ -2.5. \(^g\) Identify postmenopausal women likely to have femoral neck or lumbar spine T-score ≤ -2.5. \(^h\) Identify postmenopausal women likely to have total hip, femoral neck, or lumbar spine T-score ≤ -2.5. \(^i\) OST cut-off value < 2.
4.4 Discussion

It is important that osteoporosis risk factor assessment tools are efficacious in determining individuals at risk. They also must be simple and easy to use in clinical practice. Both BW and SCORE had the lowest specificity of all screening tools reviewed. However, BW is a simple screening tool, while SCORE has a more complex algorithm. The OSIRIS and ABONE had the lowest performance in identifying individuals with low BMD and both have undergone little evaluation. Further validation of the OSIRIS, BW, and ABONE screening tools is needed. The ability of the screening tools to correctly identify women with low BMD was relatively consistent for the SCORE, ORAI, and OST regardless of the number of risk factors used. However, for clinical practice, the OST provides a quick and easy means of determining which patients would benefit most from DXA screening, while still maintaining discriminatory abilities equivalent to those of more complicated screening tools (Cadarette, et al., 2004; Geusens, et al., 2002; Gourlay, et al., 2005; Gourlay, et al., 2008; Richy, Gourlay, et al., 2004).

It is also important to restate that the purpose of these screening tools is not to diagnose osteoporosis and low BMD in postmenopausal women. They are, however, developed to aid HCPs in identifying women who are at increased risk of low BMD who should be referred for DXA screening. The assessment tools reviewed may not identify all individuals with osteoporosis, but they may help to increase the efficiency of referrals for DXA screening.

The assessment tools were developed based on specific clinical risk factors found to be significant predictors of low BMD. There are apparent similarities in the risk factors used among screening tools. Advancing age, low body weight, and HT use have been
shown to be significant predictors of osteoporosis and were commonly used in most of the screening tool algorithms (Dargent-Molina, Poitiers, & Breart, 2002). Interestingly, performance of the assessment tools across younger and older postmenopausal women yielded inconsistent results (Gourlay, et al., 2005; Mauck, et al., 2005; Sedrine, et al., 2001; Ungar, et al., 2000). These inconsistencies can be best explained by the differences in sample populations to whom the screening tools were applied. As a screening assessment, the BW criterion alone (< 70 kg) has shown good performance. For example, Cadarette et al. (2001) found that BW criterion correctly identified 87% of postmenopausal women with osteoporosis at the femoral neck. Gourlay et al. (2008) found that body weight with a cut-off < 57.7 kg yielded an AUC of 0.73 among postmenopausal women 67 years of age and older. HT use was also a risk factor used in algorithms for SCORE, ORAI, and ABONE. However, since the Women’s Health Initiative reported the risks of estrogen and progestin therapy in postmenopausal women, HT use is not as prevalent in this age group and, therefore, may not be as relevant today.

In the development cohorts, two of the screening tools reviewed (SCORE and ORAI) used T-scores ≤ -2.0 to target those at risk of low BMD, while OST, BW, ORISIS, and ABONE use T-scores ≤ -2.5 to identify those who require screening. Several of the studies reviewed also evaluated the screening tools using different T-score thresholds and screening sites and found that the results were still appreciable (Cadarette, et al., 2004; Gourlay, et al., 2005; Mauck, et al., 2005; Ungar, et al., 2000). With early detection, proper management and treatment of osteoporosis can be provided. DXA screening can allow individuals with both early and later stages of the disease to be identified, so that measures to control the disease may be initiated. Ultimately, T-score
thresholds should correctly identify those with low BMD who need screening (high sensitivity), and exclude those who have normal BMD levels (high specificity). Screening tools using T-scores \(\leq -2.0\) had excellent performance identifying individuals with low BMD and may ultimately limit the risk of osteoporotic fractures and overall health care expenditures.

The six screening assessments reviewed in this paper were developed using postmenopausal women of Caucasian majority, with the exception of the OST which was developed in Asian women (Koh, et al., 2001). Since this time, several studies have validated the OST in other ethnic populations, as well as in men (Cass, Shepherd, & Carlson, 2006). There is still a need, however, for further validation of these screening tools in men, and to establish cut-off values in more diverse samples of ethnic groups.

The practical application and effectiveness of these screening tools in a clinical setting has yet to be assessed. Given the overall consistency of results across screening tools, future research should now be directed at incorporating these tools into clinical practice to determine their effectiveness. There also still remains a great deal of uncertainty regarding the generalizability of these screening tools across different populations, including various ethnicities, males, and age groups of peri- and postmenopausal women. Future research should also continue to explore the economic impact of the use of osteoporosis risk factor assessment tools in clinical practice. A recent study carried out by Richy et al. (2004) compared the cost-effectiveness of screening tools in 4,035 postmenopausal Caucasian women. Results showed pre-screening with SCORE, OST, ORAI, and OSIRIS with threshold scores indicating medium and high risk of osteoporosis, identified 75% to 89% of women, with a consistently reduced cost for
each individual detected. These results have great implications for public health regarding the usefulness of screening tools in alleviating the economic burden of DXA screening.

4.5 Conclusion

Measuring BMD by DXA remains the single best method for predicting fracture risk, and diagnosing osteoporosis; however, measuring BMD by DXA is not feasible in most countries due to the costs and limited availability of DXA machines. The risk factor assessments tools reviewed may provide a useful and efficacious means for HCPs to determine postmenopausal women who are at increased risk of osteoporosis and low BMD and would benefit from DXA screening. The OST appears to be the easiest screening tool to use while still maintaining acceptable discriminatory abilities.
CHAPTER 5: STUDY 2
5.1 Introduction

Osteoporosis and consequent fragility fractures are a major public health concern in Canada, predominantly in older men and women. Osteoporosis and its related fractures cause increased morbidity, mortality, and reduced quality of life. With incidence of osteoporosis and related fractures expected to rise with Canada’s rapidly aging population, these adverse consequences also extend to the growing health care expenditures for treating the disease (Ioannidis, et al., 2009; Papaioannou, et al., 2009; Tarride, et al., 2012; Wiktorowicz, et al., 2001). Although significant advances have been made in the management of osteoporosis, it is widely recognized that prevention of the disease and its related fractures is essential to reduce risk. Therefore, diagnostic screening, a primary and secondary prevention intervention for osteoporosis, plays an important role.

The current diagnostic criteria for management of osteoporosis, defined by the World Health Organization (WHO), are based on measurement of bone mineral density (BMD) assessed by dual energy x-ray absorptiometry (DXA) (WHO, 1994). Based on a recently revised protocol for diagnosis and management of osteoporosis in Canada, men and women over 50 years of age should be routinely screened for osteoporosis risk factors to identify those at high risk (Papaioannou, et al., 2010). These Canadian clinical practice guidelines outline risk factor indicators for selecting individuals who should undergo DXA screening – an important component of the practice guidelines, which use an integrated approach for the management and treatment of osteoporosis and fractures (Papaioannou, et al., 2010). However, despite these practice guidelines, only a minority of Canadians are referred for screening, suggesting that screening on the basis of clinical
guidelines may not be practical from a public health perspective (Jiwa, et al., 2008). Reasons for this may be largely due to lack of access to screening, especially for individuals living in rural areas. In Canada, accessibility to DXA screening varies from province to province. For example, in Saskatchewan, only three DXA machines operate province-wide, a shortage recognized by the provincial Health Quality Council report and the Osteoporosis Canada report on BMD screening services, which graded the province an “F” for insufficient screening (Jiwa, et al., 2008; McCulloch, et al., 2003). DXA units and the assessment are also costly, requiring trained technicians for operation. These factors contribute to the challenge of preventing and managing the disease, and identifying individuals who could possibly benefit from treatment.

Interest in the use of simple, reliable, and cost-effective screening tests such as QUS, and clinical risk factor assessment tools such as OST, have increased in their potential to diagnose osteoporosis or provide a quick and easy means of identifying patients at risk of osteoporosis who should be referred for diagnostic screening (Collinge, et al., 2010; Edelmann-Schafer, et al., 2011; Koh, et al., 2001; McLeod & Johnson, 2008). While neither OST nor QUS can be used to diagnose osteoporosis in terms of the WHO definition or monitor treatment, they may have potential benefits for clinicians to assist in their decision making of individuals in need of DXA screening. Additionally, they may increase screening efficiency by reducing the number of individuals referred who are otherwise healthy. However, despite numerous studies validating these tests, comparatively, their use is less known.
5.1.1 Calcaneal Quantitative Ultrasound (QUS)

Compared to DXA, QUS is radiation-free, portable, less time-consuming, and considerably lower in cost, making it practical for both research and clinical environments. QUS measurement parameters, broadband ultrasound attenuation (BUA), speed of sound (SOS), and stiffness index (SI), are generally lower in osteoporotic bone than healthy bone. A recent meta-analysis showed QUS can predict hip fracture in elderly men and women independent of risk estimates from DXA (Moayyeri, et al., 2012). However, there are no universal guidelines for identifying normal BMD versus abnormal measurement values and QUS accuracy in identifying osteoporosis remains unclear.

A meta-analysis from 2006 evaluated the discriminatory ability of QUS and found T-score cut-offs ranging from 0.0 to -2.5 were insufficient to identify individuals with or without osteoporosis; however, studies included in the analysis varied in device manufacturer, study population (age group, ethnicity, and gender), QUS parameters, and measured DXA and achilles site (Nayak, et al., 2006). Studies using the Achilles Lunar ultrasound (GE Medical, USA), which is one of the most widely tested devices among Caucasian men and women with mean age over 50 years, show QUS and DXA are moderately correlated ($r = 0.288$ to $0.694$) with AUC range of .706 to .909 at the spine or femoral neck (Bachman, et al., 2002; Collinge, et al., 2010; Edelmann-Schafer, et al., 2011; Gemalmaz, et al., 2007; Sorensen, et al., 2001). Notably, a majority of the study populations’ age ranges included men and women less than 50 years, and the two studies including men did not evaluate genders separately. Canadian practice guidelines concentrate on the assessment and management of men and women 50 years of age and older, due to the burden of illness in this group (Papaioannou, et al., 2010). Therefore, in
order for QUS parameters to be reliably applied, the impact of age and sex on the relationship between QUS and DXA must be clarified.

The International Society for Clinical Densitometry (ISCD) has recently indicated a need for pre-defined diagnostic cut-offs of specific populations by sex, age, and ethnicity based on SI results falling above and below thresholds where, ideally, sensitivity and specificity exceeds 90%, respectively (Hans & Krieg, 2009). Currently, cut-offs proposed in the research literature are limited for both older men and women. An assessment of 5,954 Caucasian women 75 years and older taking part in the EPIDOS Study (France) showed high diagnostic accuracy of the Achilles Lunar QUS with SI ≤ 57 and low likelihood of osteoporosis with SI > 78 in postmenopausal women (Hans & Krieg, 2009). To our knowledge, no study has identified potential diagnostic thresholds in Canadian men and women over 50 years of age.

5.1.2 Osteoporosis Self-Assessment Tool (OST)

Of the clinical risk factor assessment tools developed to objectively select older men and women who would benefit from diagnostic screening, the Osteoporosis Self-Assessment Tool (OST) has been determined to be the most reliable in a systematic review (McLeod & Johnson, 2008). OST has undergone extensive validation, particularly in postmenopausal women, and has demonstrated better discriminative performance with use of only two risk factors, age and body weight, in its algorithm compared to other decision tools (Koh, et al., 2001; McLeod & Johnson, 2008). Results from several large validation cohorts of Caucasian postmenopausal women from Belgium, United States, and Netherlands suggest a cut-off of < 2, defined to detect approximately 90% of women
with low BMD, despite a high proportion of false-positive results (Geusens, et al., 2002; Richy, Gourlay, et al., 2004).

A meta-analysis assessing the performance of OST found that it performed moderately (summary likelihood ratio of negative test result, sLR- = 0.19, 95% CI, 0.17-0.21) in excluding postmenopausal Caucasian women with femoral neck T-score ≤ -2.5, but poorly (sLR- = 0.43, 95% CI 0.31-0.43) when excluding lumbar spine T-score ≤ -2.5 (Rud, et al., 2007). An update of this meta-analysis found OST accuracy was higher at the femoral neck in white postmenopausal women compared to other risk factor assessment tools (Rud, et al., 2009). However, the authors mentioned several limitations of the methodological quality of the studies including the use of retrospective data, and inadequate reporting of study sample characteristics, withdrawals, and uninterpretable test results (Rud, et al., 2007, 2009). Studies evaluating the performance of OST in men and women have used various dichotomous cut-off scores and DXA screening sites to optimize discrimination (Adler, et al., 2003; Cook, et al., 2005; Skedros, Sybrowsky, & Stoddard, 2007). As previously mentioned, a cut-off < 2 in postmenopausal women has been suggested for DXA referral; however, similar data are lacking for older men. Adler, Tran, and Petkov (2003) suggested a cut-off < 3 to predict osteoporosis in men (n = 181, $M_{age} = 64.3$ years), with a sensitivity of 93% and specificity of 66%.

Research literature assessing the comparative use of QUS and OST is limited. Rud et al. (2009) found QUS SI (Achilles Lunar ultrasound, GE Medical) was more accurate than OST regardless of BMD site in white postmenopausal women; however, these studies were reported as abstracts. To our knowledge, no studies have compared the accuracy of QUS and OST to DXA in older, community-dwelling men and women.
attending a primary care setting. The aim of this study was to examine the relationship between QUS, OST, and DXA, and to evaluate the accuracy of calcaneal QUS and OST in identifying men and women over 50 years of age with osteoporosis as defined by DXA. A further aim of the study was to determine optimal cut-offs for QUS and OST to identify osteoporosis risk in this population.

5.2 Methods

5.2.1 Participants

Male and female patients referred by their HCP for DXA screening to the department of Nuclear Medicine at the Regina General Hospital (Regina, SK) over a 14-month period (July 2010 to September 2011) were considered for enrollment in the study. A priori power analysis identified a necessary sample size of at least 200 based on statistical power of 0.80, a minimum effect size of 0.20, and two-tailed alpha of 0.05 for a hypothesized AUC of at least 0.75 by G*Power 3.1 software (Faul, Erdfelder, Lang, & Buchner, 2007). Men and women were included in the study if they were 50 years of age and older, referred for a DXA screening by their HCP, received DXA screening for the first time, and were willing to sign a letter of informed consent. The target population was men and women over 50 years of age due to the overall burden of the disease in this age group (Papaioannou, et al., 2010). Referral for DXA screening by HCPs was based on clinical risk factors and/or diagnostic judgment of the HCP. Excluding factors used to determine the final eligible study population included previous diagnosis and/or treatment for osteoporosis, having a progressive terminal illness that requires intensive medical care (e.g., cancer, congestive heart failure), receiving palliative care, or advanced cognitive
impairment of any kind that would preclude the participant from understanding the letter of information and signing the informed consent.

5.2.2 Recruitment and Screening Procedures

Recruitment flyers were placed in waiting areas throughout the Nuclear Medicine Department at the hospital. The DXA technician also played a critical role in the recruitment process. During each diagnostic screening the technician identified potential participants based on preliminary inclusion criteria: men and women age 50 years of age and older and receiving DXA screening for the first time. They served as the initial “face” of the study by briefly describing the study to potential participants, providing invitation letters containing study and contact information, and completing a postcard for each interested patient who agreed to be contacted. The completed postcard included the patient’s name, phone number, and screening date. The postcards were collected weekly by the primary researcher for telephone follow-up.

Men and women interested in the study (based on postcard collection) were contacted, questions about the study were answered, and they were screened for eligibility. The postcards proved to be the best method of recruitment. If initial contact was not made, a voicemail was left reminding them of the study and their interest, and kindly asked them to respond at their earliest convenience. If there was no response after two days, follow-up calls were made. This follow-up method also proved to be very successful. Several interested participants also responded via telephone or email within days of their DXA screening based on the letter of invitation. Those responding by email were followed-up by telephone and the same eligibility screening procedure was followed. For all individuals deemed eligible, a baseline appointment was scheduled and
a questionnaire and consent package was mailed to their home. It was important to recruit, make initial contact, screen for eligibility, and schedule eligible participants’ baseline visit within two to three weeks of their DXA screening as most HCP’s would receive patient DXA screening results within three to four weeks. This helped to ensure participants completed baseline prior to discussing their DXA results with their HCP. In cases where contact was finally made with a potential participant after three weeks (e.g., the individual was out of town), questions in the eligibility screening helped to determine whether they had discussed results with their HCP (e.g., “Have you discussed your bone density screening results with your doctor?”). This often prompted discussion of a potential upcoming appointment with their HCP, in which case participants were amenable to scheduling baseline prior to their appointment. Incentives for participation included a one-day pass to the Fitness and Lifestyle Centre at the University of Regina, a free university parking pass to use at all study visits, and upon completion of follow-up, participants names were entered into one of three $100 draws and one of 10 gift certificate draws.

The DXA screening rate at the hospital was approximately 20 screenings per day or 400 screenings per month. Based on this screening rate and the strict inclusion criteria, an 8-month inclusion period was anticipated to recruit 200 participants. However, throughout the recruitment phase, several unforeseen events or factors hindered this timeline, extending it to a 14-month recruitment phase. This included training of new DXA technicians, DXA technician illness/surgery, and holidays, which reduced typical screening rates, quality assurance testing of the DXA unit, and lower screening rates of first-time patients (many patients were receiving follow-up DXA screening).
During the course of the study, 298 patients who underwent DXA screening were identified as potentially eligible for enrollment based on age and first-time screening. Of these, we were unable to contact 39, and 34 declined study screening as they were not interested or unable to participate. Of the remaining 225 screening for eligibility, three were deemed ineligible due to osteoporosis treatment use or advanced cognitive impairment and 18 were unwilling to participate after scheduling for the following reasons: death in the family/personal reasons, too busy/no time, no longer interested/multiple unexcused cancellations, and too many questionnaires to complete. A total of 204 men and women were included in the study and provided informed consent.

5.2.3 Study Design and Procedure

This was a cross-sectional study, conducted at the Centre for Exercise and Nutrition in Falls and Aging Research (CENFAR) at the University of Regina. All participants consecutively underwent DXA screening at the hospital and were scheduled for a baseline visit to CENFAR to complete subsequent measurements. Prior to their visits, participants were mailed a packet containing a map and directions to the lab, a parking permit, and a letter that thanked them for their interest and listed their baseline visit date and time. Also enclosed in the packet was a letter of information and letter of informed consent to read with instructions to be signed on the day of baseline visit, and a Background Health History Questionnaire for completion. Instructions to read the letter of information and informed consent, and complete the questionnaire were clearly provided.

Neither the participants nor the researcher were aware of DXA screening results at the time of all baseline questionnaires and measurements. Of the 204 participants
included in the study, one was excluded from the analysis as the technician was unable to perform a DXA measurement, and one was excluded as the QUS device measurement was unattainable due to swollen feet and a poor signal. The final study population included 202 men and women (174 women and 28 men, $M_{age} = 59.7$ years, age range: 50 to 80 years; see Figure 1).

5.2.4 Ethical Consideration

Prior to participant recruitment and data collection, ethical approval for the study was granted by the Research Ethics Board at the University of Regina (Identification #:70S0910) and the Regina Qu’Appelle Health Region (Identification #: REB 10-34) in accordance with the Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans*. All data were stored on a password protected secure computer at the University of Regina.
Figure 5. Flow diagram summarizing participant recruitment in Study 1.
5.2.5 Measures

Within two to four weeks of DXA screening, participants completed the Background Health History Questionnaire designed to collect information on the participant’s historical, nutritional, and lifestyle risk factors for osteoporosis, and underwent calcaneal QUS and anthropometric measures including height and weight at the University. All measurements at the institution were carried out by the same researcher.

5.2.5.1 Dual Energy X-ray Absorptiometry

A trained and certified technician from the health region measured BMD using the gold standard DXA (GE Lunar Prodigy, Madison, WI) at the lumbar spine (L1-L4), left, and right femoral neck. Absolute values of BMD for all sites measured, specifically T-scores (continuous unit), were used to categorize BMD values as normal (T-score ≥ -1), osteopenia (T-score < -1.0 to > -2.5), or osteoporosis (T-score ≤ -2.5) based on WHO diagnostic criteria. The same DXA machine was used for screening of all participants. After all participants had completed baseline, the DXA technician pulled patient charts for those who participated and photocopied DXA results, which were retrieved by the researcher.

5.2.5.2 Background Health History Questionnaire

The background questionnaire was self-administered and designed to obtain personal socio-demographic information (e.g., education, employment, marital status, and income) as well as information regarding the participants’ health history and known risk factors for osteoporosis (e.g., smoking, personal medical history including fracture history, routine consumption of calcium-fortified foods, smoking, alcohol, and caffeine.
consumption, and general physical activity habits). Questions about routine medical care including number of visits with their primary HCP in the past five years, their gender and, dosages and duration of use of medication and supplements were recorded.

5.2.5.3 Calcaneal Quantitative Ultrasound (QUS)

Participants underwent QUS measurement of the left calcaneus using a portable GE Lunar Achilles ultrasonometer (Madison, WI, USA). BUA and SOS of the calcaneus were measured. SI, which combines BUA and SOS into a single parameter ($SI = 0.67(BUA) + 0.28(SOS) – 420$) established by the manufacturer, was also calculated and converted into a T-score. An SI $\leq 57$ has been proposed recently in literature to identify high likelihood of osteoporosis in postmenopausal women (Hans & Krieg, 2009). To ensure quality control, the QUS unit was calibrated daily prior to measurements using the phantom supplied by the manufacturer. The ultrasound measurement took 10 minutes for each participant, including data entry, participant preparation, positioning, and measurement.

5.2.5.4 Anthropometric Assessments

Wearing a bathing suit (women) or shirtless and compression shorts (men), participants’ body weight was measured using a calibrated digital scale to the nearest 0.01 kg. Height was determined using a portable stadiometer with weighing scale and measured to the nearest centimeter.

5.2.5.5 Osteoporosis Self-Assessment Tool (OST)

OST was calculated according to the algorithm suggested by the developer: 

$\lfloor 0.2(weight \ in \ kg – age) \rfloor$ truncated to an integer (Koh, et al., 2001). OST was originally developed in Asian women, but has since been validated in Caucasian women and men.
with cut-offs < 2 and < 3 respectively, signifying moderate-to-high risk and
recommendation for DXA screening (Adler, et al., 2003; Koh, et al., 2001; Richy,
Gourlay, et al., 2004; Rud, et al., 2005).

5.3 Statistical Analysis

Descriptive statistics were computed for demographic variables and risk factors
for osteoporosis, as well as DXA T-score level (lowest of three sites reported) and site
QUS SI and T-score, and OST scores. Continuous variables were expressed as means and
standard deviations. Categorical variables were summarized as counts and proportions.
Pearson correlation coefficients were calculated to examine the association between QUS
(SI and T-score), OST, and DXA parameters in men and women (T-score of lumbar spine
and femoral neck lowest of two sites reported).

5.3.1 Sensitivity, Specificity, and Likelihood Ratios

To assess the ability of QUS and OST to discriminate between men and women
with osteoporosis (T-score ≤ -2.5) defined by DXA (lumbar spine and femoral neck),
receiver operating characteristic (ROC) curves were constructed and the area under the
curves (AUCs) with 95% confidence intervals were computed. ROC analysis summarizes
sensitivity (correctly identifying individuals who have osteoporosis; true-positive rate),
and specificity (correctly identifying individuals who have normal or low BMD; true-
negative rate) of the screening tool (Streiner & Cairney, 2007). As shown in Table 5, the
discriminatory ability of a screening tool, also referred to as diagnostic accuracy, defines
the level of agreement between the index test (QUS and OST) and the reference standard
(DXA) (Florkowski, 2008).
Table 5

Diagnostic Accuracy Outcomes Based on DXA Result

<table>
<thead>
<tr>
<th>Reference Standard (DXA) Result</th>
<th>Disease Present</th>
<th>Disease Absent</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index Test Result (QUS and OST)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>True-positive (TP)</td>
<td>False-positive (FP)</td>
<td>TP + FP</td>
</tr>
<tr>
<td>Negative</td>
<td>False-negative (FN)</td>
<td>True-negative (TN)</td>
<td>FN + TN</td>
</tr>
<tr>
<td>Total</td>
<td>TP + FN</td>
<td>FP + FN</td>
<td></td>
</tr>
</tbody>
</table>

*Note. QUS = quantitative ultrasound; OST = Osteoporosis Self-Assessment Tool; DXA = dual energy x-ray absorptiometry; Sensitivity = TP/(TP + FN); Specificity = TN/(FP + TN).*

The ROC curves provide a graphical representation of the accuracy of a test by plotting the true-positive rate (sensitivity) against the false-positive rate (1-specificity) for all cut-offs of QUS and OST. The area under the curve (AUC) is an overall quantified estimate of the accuracy of the screening tool allowing for easy comparison of the OST and QUS test performance. The AUCs ranged from 0 to 1.00 whereby values less than 0.50 are worse than chance, and values between 0.50 and 0.70 indicates low diagnostic accuracy. AUCs of at least 0.70 to 0.80 are necessary to regard a test as efficient, and high accuracy is identified by an AUC greater than 0.90 (Streiner & Cairney, 2007). Analyses were repeated for the lumbar spine and femoral neck separately, and sex-specific curves were constructed.

The sensitivity (%), specificity (%), prevalence of osteoporosis, positive likelihood ratio (LR+) of QUS (SI and T-score) and negative likelihood ratio (LR-) of OST were calculated at various cut-offs with DXA T-score ≤ -2.5 as the reference standard. Sensitivity and specificity provide useful information regarding the diagnostic
properties of a screening tool, classifying participants as low or high risk for osteoporosis. They have an inverse relationship whereby when either of the characteristics is increased, it is at the expense of another (Streiner & Cairney, 2007).

This study focused on LR+ for QUS as its use has been based on its ability to identify individuals with low BMD, while assessment of OST performance included LR-analysis as past studies have shown it is most useful in ruling out low BMD (high sensitivity). The likelihood ratio is a clinically useful statistic for summarizing diagnostic accuracy. It provides a direct estimate of how much a test result will change the odds of having the disease. The LR+ combines information from both sensitivity and specificity \[ \text{sensitivity}/(1 – \text{specificity}) \] and represents the ratio of the proportion of individuals who have osteoporosis and test positive to the proportion of individuals without osteoporosis who also test positive (relative to the chosen cut-off) (Florkowski, 2008). The LR- \[ 1-\text{sensitivity}/(\text{specificity}) \] is the ratio of the proportion of individuals who have osteoporosis and test negative to the proportion of individuals without osteoporosis (normal BMD) and also test negative. Conveying information generated from LR+’s and LR-’s in addition to sensitivity and specificity of diagnostic test data, has been shown to enable more appropriate interpretation of test performance outcomes by clinicians (Grimes & Schulz, 2005; Steurer, Fischer, Bachmann, Koller, & Riet, 2002).

LR+ and LR- values equal to 1.00 lack diagnostic value, as individuals with and without the disease will have the same test result. LR+ values greater than 1.00 indicate better test performance in discriminating between individuals with and without osteoporosis, whereas LR- values less than 1.00 indicate the test result is associated with the absence of osteoporosis. LR’s that are further away from 1.00 provide stronger
evidence for the presence or absence of disease. A high LR+ (> 10) provides strong
evidence the test and corresponding cut-off can be used to rule in the disease, whereas an
LR- below 0.1 is considered strong evidence to rule out the disease, and values between
0.1 and 0.2 is considered moderate evidence (Grimes & Schulz, 2005).

5.3.2 Cut-off Calibration

The performance of QUS and OST was evaluated and pertinent cut-offs were
identified that provided a range of sensitivity values with corresponding specificity value.
Specific to QUS, cut-offs were calibrated based on coordinates of the ROC curves such
that lower and upper cut-offs were set to identify osteoporosis with specificity and
sensitivity greater than 90%, respectively, an approach recommended by the ISCD (Hans
& Krieg, 2009). For OST, a method based on previous studies was applied, whereby cut-
offs that achieve 90% sensitivity were identified regardless of specificity. This reflects
the decision a false-negative rate of 10% or less (1 – sensitivity) would be acceptable for
DXA referral (Koh, et al., 2001; Rud, et al., 2005). In addition to these methods, the
purpose of QUS and OST is to correctly identify individuals who have or are at high risk
of low BMD, while excluding those with normal BMD levels. Therefore, optimal cut-offs
for QUS and OST were determined by selecting the best balance between sensitivity and
specificity closest to 90%. Analyses were repeated for lumbar spine and femoral neck
separately, and stratified by sex. All results were considered statistically significant if p-
values were less than .05. Analyses were carried out using SPSS Statistics 17.0 (SPSS
Inc., Chicago, IL, USA).
5.4 Results

Participant demographics, osteoporosis risk factors, and the distribution of BMD are summarized in Table 6. Ninety-six percent of men and women were Caucasian, with the remaining 4% of Asian, First Nations or Métis decent. A total of 202 men (n = 28) and women (n = 174) included in the study had a mean age of 59.7 ± 7.1 (age range men: 51-77 years, age range women: 50 to 80 years), and a mean BMI classifying the study population as overweight (M = 27.7 ± 7.7). Majority of men and women were 50 to 64 years of age (75.7%), married or common-law (78.2%), highly educated (58.4%), and had a family history of fracture (53.0%). Of the 174 women, 80.5% were aged 50 to 64 years and 87.9% were post-menopause. Based on WHO criteria, 39.1% of men and women had normal BMD, 49.5% had osteopenia, and 11.4% were newly diagnosed with osteoporosis. Results for QUS SI, QUS T-score, and OST ranged from 45 to 148 (M = 89 ± 18.1), from -3 to 3 (M = - .7 ± 1.1), and from -7 to 15 (M = 2.7 ± 3.3), respectively.

Significant positive correlations were noted between QUS SI, T-score, OST, and DXA T-score at the lumbar spine and femoral neck (Table 7). QUS was better correlated with DXA T-score at the femoral neck (r = .512 to .517) than the lumbar spine (r = .461 to .465). OST was moderately correlated with the femoral neck (r = .437), and there was a weak correlation between OST and DXA T-scores at the lumbar spine (r = .336).
Table 6

Descriptive Characteristics and Results of DXA, QUS, and OST Measurements of the Study Population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Women (n = 174)</th>
<th>Men (n = 28)</th>
<th>Total (n = 202)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n or M (SD)</td>
<td>n or M (SD)</td>
<td>n or M (SD)</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Age</td>
<td>59.0 (6.7)</td>
<td>64.4 (7.8)</td>
<td>59.7 (7.1)</td>
</tr>
<tr>
<td>Age 50-64 years</td>
<td>140 (80.5)</td>
<td>13 (46.4)</td>
<td>153 (75.7)</td>
</tr>
<tr>
<td>Age 65-80 years</td>
<td>34 (19.5)</td>
<td>15 (53.6)</td>
<td>49 (24.3)</td>
</tr>
<tr>
<td>Body mass (kg)</td>
<td>73.4 (16.0)</td>
<td>82.9 (15.2)</td>
<td>74.7 (16.2)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.7 (5.6)</td>
<td>27.7 (4.6)</td>
<td>27.7 (5.5)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>13 (7.5)</td>
<td>1 (3.6)</td>
<td>14 (6.9)</td>
</tr>
<tr>
<td>Married/common-law</td>
<td>134 (77.0)</td>
<td>24 (85.7)</td>
<td>158 (78.2)</td>
</tr>
<tr>
<td>Divorced/widowed</td>
<td>27 (15.5)</td>
<td>3 (10.7)</td>
<td>30 (14.9)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary/high-school</td>
<td>70 (40.2)</td>
<td>14 (50.0)</td>
<td>84 (41.6)</td>
</tr>
<tr>
<td>University/post-grad</td>
<td>104 (59.8)</td>
<td>14 (50.0)</td>
<td>118 (58.4)</td>
</tr>
</tbody>
</table>
Table 6 (continued)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Women (n = 174)</th>
<th>Men (n = 28)</th>
<th>Total (n = 202)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n or M (SD)</td>
<td>%</td>
<td>n or M (SD)</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>82</td>
<td>47.1</td>
<td>12</td>
</tr>
<tr>
<td>Past</td>
<td>63</td>
<td>36.2</td>
<td>15</td>
</tr>
<tr>
<td>Current</td>
<td>19</td>
<td>10.9</td>
<td>1</td>
</tr>
<tr>
<td>HT use</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Never</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Past</td>
<td>27</td>
<td>15.5</td>
<td>N/A</td>
</tr>
<tr>
<td>Glucocorticoid use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>166</td>
<td>95.4</td>
<td>26</td>
</tr>
<tr>
<td>Past/Current</td>
<td>8</td>
<td>4.6</td>
<td>2</td>
</tr>
<tr>
<td>Fracture after 40 years of age (yes)</td>
<td>39</td>
<td>22.4</td>
<td>6</td>
</tr>
<tr>
<td>Family history of fracture (yes)</td>
<td>96</td>
<td>55.2</td>
<td>11</td>
</tr>
</tbody>
</table>
Table 6 (continued)

| Characteristic   | Women (n = 174) | | | Men (n = 28) | | | Total (n = 202) | |
|------------------|----------------|----------------|----------------|----------------|----------------|----------------|
|                  | n or M (SD)    | %              | n or M (SD)    | %              | n or M (SD)    | %              |
| DXA T-score level<sup>a</sup> |               |               |               |               |               |               |
| Normal           | 74            | 42.5          | 5             | 17.9          | 79            | 39.1          |
| Osteopenia       | 82            | 47.1          | 18            | 64.3          | 100           | 49.5          |
| Osteoporosis     | 18            | 10.3          | 5             | 17.9          | 23            | 11.4          |
| DXA T-score      |               |               |               |               |               |               |
| Lumbar spine (L1-L4) | -0.6 (1.5)  | -0.6 (1.3)    | -0.6 (1.5)    |               |               |               |
| Femoral neck<sup>b</sup> | -1.0 (1.0)  | -1.6 (0.9)    | -1.1 (1.0)    |               |               |               |
| QUS              |               |               |               |               |               |               |
| Stiffness Index (SI) | 88.4 (18.1)  | 92.8 (17.9)   | 89.0 (18.1)   |               |               |               |
| T-score          | -0.7 (1.1)    | -0.5 (1.1)    | -0.7 (1.1)    |               |               |               |
| OST              | 2.6 (3.3)     | 3.2 (3.3)     | 2.7 (3.3)     |               |               |               |

Note. BMI = body mass index; QUS = quantitative ultrasound; OST = Osteoporosis Self-Assessment Tool; DXA = dual energy x-ray absorptiometry.

<sup>a</sup> Lowest T-score for three sites measured by DXA (lumbar spine, right and left femoral neck). T-score level was based on WHO definitions for normal, osteopenia, and osteoporosis.  
<sup>b</sup> Lowest of two sites (left and right femoral neck) measured.
Table 7

*Correlation Coefficients of DXA T-score, QUS parameters, and OST*

<table>
<thead>
<tr>
<th>Screening Tool</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. OST</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. QUS T-score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. QUS SI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. DXA T-score femoral neck(^a)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. DXA T-score L1-L4(^b)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. OST = Osteoporosis Self-Assessment Tool; QUS = quantitative ultrasound; SI = stiffness index; DXA = dual energy x-ray absorptiometry.

\(^a\) Lowest of two sites measured (left and right femoral neck).

\(^b\) T-score for lumbar spine L1-L4.

\(*p < .01\)
The accuracy of OST and QUS to select men and women with osteoporosis (T-score \( \leq -2.5 \)) at the femoral neck and lumbar spine are presented as AUCs in Table 8. The corresponding ROC curves are plotted in Figures 6 to 9. By tradition, the plots show sensitivity (true-positive rate) on the Y axis and 1 – specificity (false-positive rate) on the X axis. The diagonal reference line represents a test that does not discriminate between individuals with or without osteoporosis. A perfect screening tool would produce a straight line vertically up the Y axis to 1.0 and run horizontally to the right reaching 1.0. Thus, the more an ROC curve deviates from the reference line toward the top left corner, the better the sensitivity and specificity of the screening tool, and the larger the area under the curve, the more accurate the screening tool (Streiner & Cairney, 2007).

Analysis of the AUC for the ROC curves allows for comparisons between screening tools in men and women with a larger AUC (at least greater than 0.80) indicating better overall performance (Table 8). QUS was significantly better than chance as a diagnostic screening tool for osteoporosis at the femoral neck in women \((p < .001)\). Overall, the ability of QUS (SI and T-score parameters) to identify women with osteoporosis at the femoral neck \((AUC = 0.892-0.898)\) consistently out-performed QUS at the lumbar spine \((AUC = 0.696-0.698)\), and OST at both the femoral neck and lumbar spine in men and women \((AUC = 0.652-0.807)\). Notably, OST was also significantly better than chance as a diagnostic tool in women \((p < .05)\), with a high AUC \((0.807)\) for detecting osteoporosis at the femoral neck, but a lower performance \((AUC = 0.706)\) at the lumbar spine. QUS had a similar performance at the lumbar spine \((AUC = 0.696-0.698)\) as OST. Comparing the ROC curves in women, it is further evident that QUS and OST have stronger discriminatory ability at the femoral neck in women, with QUS ROC
curves superior to OST (Figure 6). Conversely, the ROC curves for QUS and OST demonstrated similar discriminatory ability at the lumbar spine (Figure 7).

Due to the small sample size of men \((n = 28)\), it is difficult to analyze and draw conclusions regarding the discriminatory power of the screening tools based on the corresponding ROC curves (Figures 8 and 9) and AUCs. In an effort to summarize these results, overall, OST performed better in men; however, both QUS and OST had low and insignificant discriminatory power with AUCs ranging from 0.570 to 0.622 and 0.652 to 0.710, respectively. This is further evidenced by the large width of 95% confidence intervals and standards of error.
Table 8

*Area Under the Receiver Operating Characteristic Curves (AUC) for QUS and OST to Identify DXA T-score ≤ -2.5 in Men and Women*

<table>
<thead>
<tr>
<th>Screening parameter</th>
<th>Women (n = 174)</th>
<th></th>
<th></th>
<th>Men (n = 28)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Femoral neck DXA T-score ≤ -2.5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Lumbar spine DXA T-score ≤ -2.5&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Femoral neck DXA T-score ≤ -2.5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Lumbar spine DXA T-score ≤ -2.5&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>AUC</strong></td>
<td><strong>SE</strong></td>
<td><strong>95% CI</strong></td>
<td><strong>AUC</strong></td>
<td><strong>SE</strong></td>
<td><strong>95% CI</strong></td>
<td></td>
</tr>
<tr>
<td>OST</td>
<td>0.807*</td>
<td>0.091</td>
<td>[0.692, 0.985]</td>
<td>0.652</td>
<td>0.117</td>
<td>[0.424, 0.881]</td>
</tr>
<tr>
<td>QUS SI</td>
<td>0.892***</td>
<td>0.042</td>
<td>[0.809, 0.975]</td>
<td>0.622</td>
<td>0.149</td>
<td>[0.316, 0.919]</td>
</tr>
<tr>
<td>QUS T-score</td>
<td>0.898***</td>
<td>0.041</td>
<td>[0.817, 0.978]</td>
<td>0.617</td>
<td>0.154</td>
<td>[0.329, 0.915]</td>
</tr>
</tbody>
</table>

*Note.* OST = Osteoporosis Self-Assessment Tool; QUS = quantitative ultrasound; SI = stiffness index; DXA = dual energy x-ray absorptiometry; CI = confidence interval; AUC = area under receiver operating characteristic; Reference variable defined as femoral neck and lumbar spine T-score ≤ -2.5 for OST, QUS SI, and QUS T-score.  
<sup>a</sup>Lowest of two sites measured (left and right femoral neck).  
<sup>b</sup>T-score for lumbar spine L1-L4.  
*<sup>p</sup> < .05  **<sup>p</sup> < .001
Figure 6. ROC curves for OST, QUS SI, and QUS T-score based on DXA (femoral neck) T-score \( \leq -2.5 \) in women. Sensitivity = True-positive rate; \( 1 - \) Specificity = False-positive rate.
Figure 7. ROC curves for OST, QUS SI, and QUS T-score based on DXA (lumbar spine) T-score ≤ -2.5 in women. Sensitivity = True-positive rate; 1 – Specificity = False-positive rate.
Figure 8. ROC curves for OST, QUS SI, and QUS T-score based on DXA (femoral neck) T-score ≤ -2.5 in men. Sensitivity = True-positive rate; 1 – Specificity = False-positive rate.
Figure 9. ROC curves for OST, QUS SI, and QUS T-score based on DXA (lumbar spine) T-score ≤ -2.5 in men. Sensitivity = True-positive rate; 1 – Specificity = False-positive rate.
The performance of each screening tool in identifying women with osteoporosis (T-score ≤ -2.5 at the femoral neck and lumbar spine) are shown in Tables 9 and 10, with pertinent cut-off values from the ROC curves and their associated sensitivity, specificity, prevalence, and LR+ summarized. Overall, with a decreasing cut-off, sensitivity decreased and specificity increased for QUS and OST. Utilizing the “lower” and “upper” cut-off approach to identify osteoporosis with 90% specificity and sensitivity, respectively, a QUS T-score cut-off less than -2.15 and SI cut-off less than 65 achieved 91.6% specificity for identifying osteoporosis at the femoral neck (Table 9). At the same BMD site, an 87.5% sensitivity threshold yielded a T-score cut-off greater than -1.35 and an SI cut-off greater than 78. Using these lower (specificity) and upper (sensitivity) cut-offs generated 8.4% false-positive and 12.5% false-negative results. At the lumbar spine, to achieve a specificity close to 90%, cut-offs were similar to those at the femoral neck (T-score < -2.15 and SI < 66); however, upper (sensitivity) cut-offs were much higher, with T-score greater than 0.25 and SI greater than 104.

An effort was also made to explore QUS cut-offs maximizing a balance between sensitivity and specificity in order to identify high risk of osteoporosis while excluding those with normal BMD based on DXA. At the femoral neck, these cut-offs corresponded to a T-score of -2.05 and SI of 68. At the lumbar spine, optimal QUS cut-offs were far below the 90% balance of sensitivity (64.3%) and specificity (66.9%), with T-score less than -1.25 and SI less than 80.

Overall, the prevalence of osteoporosis in women was higher at the lumbar spine (8.0%, 14/174) than the femoral neck (4.6%, 8/174). In practical terms, increasing prevalence of osteoporosis at the femoral neck and lumbar spine with decreasing cut-offs
was apparent for QUS. For example, using the femoral neck and lumbar spine lower cut-offs, 26.3% and 23.8% of women had osteoporosis, respectively. Using the same cut-offs, a LR+ of 7.44 or higher at the femoral neck, indicated substantially increased likelihood of osteoporosis than those who have normal BMD, reinforcing the high diagnostic performance of QUS at this site compared to the lumbar spine (LR+ 4.06). Similar results were found using cut-offs based on optimal balance between sensitivity and specificity with femoral neck LR+ ranging from 6.94 to 7.35, but only slightly increased odds at the lumbar spine (LR+ 1.94). Adjusting specificity to 99.4% yielded an even lower cut-off at the femoral neck (SI < 56) and a much higher LR+ of 20.83. Similarly, a specificity of 98.1% at the lumbar spine yielded an SI < 60 and a LR+ of 11.26. Notably, LR+ remained higher at the femoral neck.

For OST, lower cut-offs represent higher risk of osteoporosis (Table 10). The OST cut off that achieved close to 90% sensitivity (87.5%) for identifying women with osteoporosis at the femoral neck was < 2, with specificity of 62.7%. In addition, this cut-off yielded an optimal balance between sensitivity and specificity. At the lumbar spine, it was necessary to use a much higher OST cut-off (< 5) to achieve approximately the same sensitivity (85.7%), compared to the femoral neck. Optimal balance of sensitivity and specificity was achieved with a cut-off < 2, equivalent to the femoral neck.

Using the femoral neck and lumbar spine OST cut-off < 2, prevalence of osteoporosis was 6.9% (7/101) and 10.9% (11/101), respectively. At the lumbar spine, women with osteoporosis would be 0.34 times less likely to have a negative test result than a woman with normal BMD or osteopenia (OST LR- = 0.34). At the femoral neck,
OST had a lower LR- of 0.20, showing women with osteoporosis were only one-fifth as likely to have a negative test result as women without normal BMD or osteopenia.
Table 9

*Sensitivity, Specificity, and Positive Likelihood Ratio of QUS at Pertinent Cut-offs to Identify DXA T-score ≤ -2.5 at the Femoral Neck and Lumbar Spine in Women*

<table>
<thead>
<tr>
<th>Screening parameter</th>
<th>Femoral neck DXA T-score ≤ -2.5&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Lumbar spine DXA T-score ≤ -2.5&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cut-off</td>
<td>Sensitivity (%)</td>
</tr>
<tr>
<td>QUS SI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>56</td>
<td>12.5</td>
<td>99.4</td>
</tr>
<tr>
<td>58</td>
<td>12.5</td>
<td>98.2</td>
</tr>
<tr>
<td>65</td>
<td>62.5</td>
<td>91.6</td>
</tr>
<tr>
<td>68</td>
<td>75.0</td>
<td>89.2</td>
</tr>
<tr>
<td>78</td>
<td>87.5</td>
<td>70.5</td>
</tr>
<tr>
<td>80</td>
<td>100</td>
<td>67.5</td>
</tr>
<tr>
<td>QUS T-score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-2.80</td>
<td>12.5</td>
<td>99.4</td>
</tr>
<tr>
<td>-2.65</td>
<td>12.5</td>
<td>98.2</td>
</tr>
<tr>
<td>-2.15</td>
<td>62.5</td>
<td>91.6</td>
</tr>
<tr>
<td>-2.05</td>
<td>75.0</td>
<td>89.8</td>
</tr>
<tr>
<td>-1.35</td>
<td>87.5</td>
<td>71.7</td>
</tr>
<tr>
<td>-1.25</td>
<td>100</td>
<td>67.5</td>
</tr>
</tbody>
</table>

*Note. QUS = quantitative ultrasound; SI = stiffness index; DXA = dual energy x-ray absorptiometry; Sensitivity (%) = true-positive rate; Specificity (%) = true-negative rate; LR+ = positive likelihood ratio.*

<sup>a</sup>*Lowest of two sites measured (left and right femoral neck).*

<sup>b</sup>*T-score for lumbar spine L1-L4.*
Table 10

Sensitivity, Specificity, and Negative Likelihood Ratio of OST at Pertinent Cut-offs to Identify DXA T-score ≤ -2.5 at the Femoral Neck and Lumbar Spine in Women

<table>
<thead>
<tr>
<th>Screening parameter</th>
<th>Femoral neck DXA T-score ≤ -2.5&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Lumbar spine DXA T-score ≤ -2.5&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity (%)</td>
<td>Specificity (%)</td>
</tr>
<tr>
<td>OST</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; -3</td>
<td>25.0</td>
<td>98.8</td>
</tr>
<tr>
<td>0</td>
<td>50.0</td>
<td>91.6</td>
</tr>
<tr>
<td>&lt; 2</td>
<td>87.5</td>
<td>62.7</td>
</tr>
<tr>
<td>&lt; 3</td>
<td>87.5</td>
<td>43.4</td>
</tr>
<tr>
<td>&lt; 5</td>
<td>87.5</td>
<td>23.5</td>
</tr>
<tr>
<td>&lt; 6</td>
<td>100</td>
<td>16.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. OST = Osteoporosis Self-Assessment Tool; DXA = dual energy x-ray absorptiometry; Sensitivity (%) = true-positive rate; Specificity (%) = true-negative rate; LR- = negative likelihood ratio.

<sup>a</sup> Lowest of two sites measured (left and right femoral neck). <sup>b</sup>T-score for lumbar spine L1-L4
Tables 11 and 12 summarize the pertinent cut-off values for QUS and OST and their associated sensitivity, specificity, prevalence, and positive LRs in identifying men with osteoporosis (T-score ≤ -2.5 at the femoral neck and lumbar spine). For both QUS and OST, with decreasing cut-off values, sensitivity decreased and specificity increased. It is important to reiterate, that the ROC curves, and more specifically the AUC, are a reflection of the discriminatory ability of a screening tool. As previously shown in Table 8 and Figures 8 and 9, both QUS and OST had low accuracy and large confidence intervals (AUC = 0.570-0.710, 95% CI: 0.00-1.00), producing inaccurate estimates (sensitivity and specificity) in men. Sensitivity and specificity of a screening test depends on the cut-off values chosen from the ROC curve; therefore, while effort was made to identify optimal cut-offs, they must be interpreted with caution.

Lower QUS cut-offs set to identify osteoporosis with close to 90% specificity were T-score of -2.05 and SI of 68, achieving 95.7% and 92% specificity at the femoral neck and lumbar spine, respectively (Table 11). These cut-offs were similar to those achieved in women and generated 4.3% and 8% false-positive results. Upper cut-offs of 0.70 (T-score) and 106 (SI) achieved 100% sensitivity at both BMD sites.

Overall, the prevalence of osteoporosis in men was higher at the femoral neck (17.9%, 5/28) than the lumbar spine (7.1%, 2/28), with increasing prevalence corresponding to decreasing cut-offs. Using the lower QUS cut-offs, 2 out of 3 men (66.7%) had osteoporosis at the femoral neck and were nearly nine times as likely as those with normal BMD or osteopenia to be classified as having the disease. At the lumbar spine, 1 out of 3 men (33.3%) had osteoporosis and the LR+ was 6.25. As
specificity decreased, so did LR+ indicating significantly reduced odds, which also corresponds to the low AUCs.

For OST, to define osteoporosis (T-score ≤ -2.5) at the femoral neck and lumbar spine, a cut off < 5 achieved a sensitivity of 100% and specificity of 34.8% and 28%, respectively. The high sensitivity at this cut-off was supported by a lower LR- of 0 suggesting a negative test will effectively rule out osteoporosis.
Table 11

*Sensitivity, Specificity, and Positive Likelihood Ratio of QUS at Pertinent Cut-offs to Identify DXA T-score ≤ -2.5 at the Femoral Neck and Lumbar Spine in Men*

<table>
<thead>
<tr>
<th>Screening parameter</th>
<th>Femoral neck DXA T-score ≤ -2.5&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Lumbar spine DXA T-score ≤ -2.5&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cut-off</td>
<td>Sensitivity (%)</td>
</tr>
<tr>
<td>QUS SI</td>
<td>64</td>
<td>20.0</td>
</tr>
<tr>
<td></td>
<td>68</td>
<td>40.0</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td>40.0</td>
</tr>
<tr>
<td></td>
<td>95</td>
<td>80.0</td>
</tr>
<tr>
<td></td>
<td>106</td>
<td>100</td>
</tr>
<tr>
<td>QUS T-score</td>
<td>- 2.05</td>
<td>40.0</td>
</tr>
<tr>
<td></td>
<td>- 1.35</td>
<td>40.0</td>
</tr>
<tr>
<td></td>
<td>- 1.25</td>
<td>40.0</td>
</tr>
<tr>
<td></td>
<td>- 0.35</td>
<td>80.0</td>
</tr>
<tr>
<td></td>
<td>0.70</td>
<td>100</td>
</tr>
</tbody>
</table>

*Note.* QUS = quantitative ultrasound; SI = stiffness index; DXA = dual energy x-ray absorptiometry; Sensitivity (%) = true-positive rate; Specificity (%) = true-negative rate; LR+ = positive likelihood ratio.

<sup>a</sup>Lowest of two sites measured (left and right femoral neck).  
<sup>b</sup>T-score for lumbar spine L1-L4.
Table 12

Sensitivity, Specificity, and Negative Likelihood Ratio of OST at Pertinent Cut-offs to Identify DXA T-score ≤ -2.5 at the Femoral Neck and Lumbar Spine in Men

<table>
<thead>
<tr>
<th>Screening parameter</th>
<th>Cut-off</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>Prevalence (%)</th>
<th>LR-</th>
<th>Cut-off</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>Prevalence (%)</th>
<th>LR-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral neck</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DXA T-score ≤ -2.5</td>
<td>0</td>
<td>20.0</td>
<td>100</td>
<td>16.7 (1/6)</td>
<td>0.80</td>
<td>0</td>
<td>50.0</td>
<td>100</td>
<td>16.7 (1/6)</td>
<td>0.50</td>
</tr>
<tr>
<td></td>
<td>&lt; 2</td>
<td>40.0</td>
<td>65.2</td>
<td>21.4 (3/14)</td>
<td>0.92</td>
<td>&lt; 2</td>
<td>50.0</td>
<td>64.0</td>
<td>7.1 (1/14)</td>
<td>0.78</td>
</tr>
<tr>
<td></td>
<td>&lt; 3</td>
<td>60.0</td>
<td>52.2</td>
<td>27.8 (5/18)</td>
<td>0.77</td>
<td>&lt; 3</td>
<td>50.0</td>
<td>48.0</td>
<td>11.1 (2/18)</td>
<td>1.04</td>
</tr>
<tr>
<td></td>
<td>&lt; 5</td>
<td>100</td>
<td>34.8</td>
<td>21.7 (5/23)</td>
<td>0.00</td>
<td>&lt; 5</td>
<td>100</td>
<td>28.0</td>
<td>8.7 (2/23)</td>
<td>0.00</td>
</tr>
<tr>
<td></td>
<td>&lt; 6</td>
<td>100</td>
<td>21.7</td>
<td>20.8 (5/24)</td>
<td>0.00</td>
<td>&lt; 6</td>
<td>100</td>
<td>20.0</td>
<td>8.3 (2/24)</td>
<td>0.00</td>
</tr>
</tbody>
</table>

| Lumbar spine        |         |                |                |               |     |         |                |                |               |     |
| DXA T-score ≤ -2.5  | 0       |                |                |               |     |         |                |                |               |     |
|                     | < 2     |                |                |               |     |         |                |                |               |     |
|                     | < 3     |                |                |               |     |         |                |                |               |     |
|                     | < 5     |                |                |               |     |         |                |                |               |     |
|                     | < 6     |                |                |               |     |         |                |                |               |     |

Note. OST = Osteoporosis Self-Assessment Tool; DXA = dual energy x-ray absorptiometry; Sensitivity (%) = true-positive rate; Specificity (%) = true-negative rate; LR- = negative likelihood ratio.

* Lowest of two sites measured (left and right femoral neck). * T-score for lumbar spine L1-L4.
5.5 Discussion

The focus of the Canadian clinical practice guidelines has recently shifted from treatment of osteoporosis, to fracture prevention and treatment (Papaioannou, et al., 2010). Despite this shift, low BMD, particularly at the femoral neck, remains an important independent clinical risk factor for fracture, and its assessment by DXA is a critical and initial component of practice protocol for osteoporosis risk reduction, and the assessment of fracture risk. From a public health perspective, mass DXA screening is neither recommended nor feasible; therefore, the biggest challenge is identifying individuals at greatest risk of osteoporosis and fracture, while limiting unnecessary screening in those with normal BMD and at low risk of fracture (Jiwa, et al., 2008).

Interest in the use of calcaneal QUS and OST as simple, low-cost pre-screening tests has increased in recent years in their potential to help clinicians decide which patients have a high likelihood of osteoporosis and should undergo diagnostic DXA screening. Such pre-screening tests would also improve DXA screening efficiency and may be especially useful in communities with limited access to DXA. The relationship between QUS, OST, and DXA has been previously examined in observational studies; however, comparatively, the performance of these screening tests remains unclear. The results of this study served to compare the accuracy of QUS and OST to DXA in older community-dwelling men and women attending a primary care setting. Furthermore, the analyses sought to identify optimal parameter cut-offs for QUS and OST to identify osteoporosis risk in this population.

This study found the Achilles Lunar QUS parameters SI and T-score were statistically significant but moderately correlated with DXA T-score at the femoral neck.
(r = .512-.517, p<.05) and the lumbar spine (r = .461-.465, p<.05). These results were consistent with those found in other studies assessing the Achilles Lunar, including the observation that femoral neck BMD was better correlated with QUS than spine BMD (Collinge, et al., 2010; Pearson, et al., 2003; Sorensen, et al., 2001; Trimpou, Bosaeus, Bengstsson, & Landin-Wilhelmsen, 2010). In correlation to DXA, OST performed less effectively compared to QUS. This observation was in agreement with a previous study, although the ultrasound device employed was the CUBA Clinical QUS (Cook, et al., 2005). Similar to the QUS, in this study the femoral neck BMD (r = .437) was better correlated than the spine (r = .336). While there is limited research evaluating the relationship between OST and DXA, the correlations found in the present study were generally lower than those reported in a study by Cook, Collins, Tucker, and Zioupos (2005). This may be a reflection of the different study populations used; for example Cook et al. (2005) assessed both younger and older women, ages 29-87 years while the present study included a more clinically representative sample of men and women over 50 years of age. In addition, it has been previously shown that both BMD and QUS are negatively correlated with age and years since menopause, which may contribute to the difference in correlation coefficients (Gemalmaz, et al., 2007).

The diagnostic accuracy of QUS and OST in men and women was determined by ROC analysis and computing the AUC. As previously mentioned, AUCs greater than 0.70 suggest a screening test is efficient, and an AUC greater than 0.90 indicates high diagnostic accuracy (Streiner & Cairney, 2007). In women, both QUS parameters and OST were better able to discriminate between those with and without osteoporosis at the femoral neck (AUC = 0.807-0.898) compared to the spine (AUC = 0.696- 0.706). These
results are promising in that Canadian clinical practice guidelines recommend only femoral neck BMD be used to calculate osteoporotic fracture risk in individuals older than 50 years (Papaioannou, et al., 2010). Results of previous studies assessing the diagnostic accuracy of the Achilles Lunar QUS device or OST in older women (AUC of the femoral neck = 0.760-0.909 vs. AUC of the spine = 0.686-0.710) are consistent with the present study, suggesting both screening tests may be most useful in predicting high risk of low BMD at the femoral neck (Brand, et al., 2008; Edelmann-Schafer, et al., 2011; Richy, Gourlay, et al., 2004; Rud, et al., 2007; Sorensen, et al., 2001). Other studies have also evaluated the performance of Achilles Lunar QUS and found approximately equivalent or marginally lower AUCs; however, these studies varied in population and design (e.g. combined analyses of men and women, ages ranging from young to old, and retrospectively collected data) (Collinge, et al., 2010; Pearson, et al., 2003). Regarding OST, a meta-analysis showed the screening test also performed moderately in ruling-out femoral neck osteoporosis but had a low performance at the lumbar spine in Caucasian women (Rud, et al., 2007). Notably, these results were somewhat overshadowed due to the poor methodological quality of the studies.

It is important to note that although both QUS and OST performed well in identifying osteoporosis at the femoral neck in women, the QUS was statistically significantly more accurate than OST. Studies comparing QUS and OST are limited. A comparative meta-analysis in postmenopausal Caucasian women found QUS SI was more accurate than OST, regardless of BMD site; but notably, there is limited utility to these results as they were reported in only four abstracts (Rud, et al., 2009). Cook et al. compared accuracy of OST and QUS using CUBA Clinical device and found a slightly
higher AUC for QUS (76.6%) compared to OST (71.6%) when identifying postmenopausal women with osteoporosis at the hip and/or lumbar spine. Although OST is appealing due to its simplicity, if it is less accurate than other relatively low-cost pre-screening tests, such as the QUS, then it should not be recommended for clinical use.

Few studies have addressed the diagnostic accuracy of QUS and OST in men. In this study the limited utility of QUS and OST in men was demonstrated by the AUCs. While this study sought to provide further insight to the diagnostic performance of these screening tools in older men, our small sample size \( (n = 28) \) does not lend itself to accurate interpretation of results. Nonetheless, the few retrospective studies in this population show promising results regarding the potential usefulness of these screening tools. For example, Adler, Tran, and Petkov (2003) evaluated 181 men with mean age of 64.3 years and found OST yielded an AUC of 0.814 at the femoral neck and 0.845 at the spine. Another study of 158 men \( (M_{\text{age}} = 67.5 \text{ years}) \), yielded an OST AUC of 0.81 and 0.69 at the femoral neck and lumbar spine, respectively (Skedros, et al., 2007). Regarding the diagnostic accuracy of QUS, a recent study combining men and women found an AUC of 0.84 at the hip (Collinge, et al., 2010). In men alone, Mulleman et al (2002) found QUS SI yielded an AUC of 0.74 in those \( (n = 66, M_{\text{age}} = 52 \text{ years}) \) who had sustained fracture. Overall, while the relationship between low BMD and fracture risk holds true in men, and current evidence suggests these screening tools may perform similarly in men and women, there is no consensus regarding the diagnostic accuracy of these screening tools in this population.

Identifying QUS and OST cut-offs that provide acceptable sensitivity and specificity for identifying individuals with osteoporosis defined by DXA is essential if
they are to be used to guide decisions for DXA screening or diagnosis. To add to the limited body of evidence and reduce the potential for misclassification, this study sought to identify optimal cut-off values specific to the Achilles Lunar QUS parameters and OST in the same population, based on gender. Presently, a major limitation of QUS and its potential use in clinical practice is the lack of consensus on the definition of device-specific cut-off values as the WHO diagnostic criteria are not applicable to QUS. Notably, in this study, using a single QUS T-score cut-off of -2.5 based on WHO diagnostic criteria would result in high specificity, but low sensitivity. Using the 90% sensitivity and specificity threshold approach recently recommended by the ISCD (Hans & Krieg, 2009), an “upper” 87.5% sensitivity cut-off yielded an SI of 78 or greater (T-score > -1.35) and a “lower” 91.6% specificity cut-off generated an SI less than 65 (T-score < -2.15) at the femoral neck in women. This high specificity corresponded to a low rate of false-positive tests (8.4%), meaning the majority of women who have QUS SI or T-score below this cut-off will be at high risk of osteoporosis. It has been proposed, that for patients below this “lower” cut-off, in this case an SI less than 65, treatment could be initiated and DXA bypassed in Caucasian women 65-74 years of age with two or more clinical risk factors (e.g. fracture history, current smoking, use of gluocorticoids, etc.) or women over 75 with one risk factor besides age (Hans & Krieg, 2009). Alternatively, the low false-negative rate (12.5%) means the risk of osteoporosis is very low. Based on the ISCD approach, results that fall between the “lower” and “upper” cut-offs would require DXA screening as a more definitive test.

The QUS T-score cut-offs chosen to detect high risk of osteoporosis at the femoral neck in women were similar to those reported by Bachman, Crewson, and Lewis
(2002) \((n = 447, M_{\text{age}} = 62 \text{ years}, \text{age range} = 45 \text{ to } 89 \text{ years})\) with an upper T-score cut-off of -1.0 at 89% sensitivity and a lower T-score cut-off of -2.5 at 92% specificity. However, Bachman et al. (2002) based analysis on lowest of three sites (lumbar spine, femoral neck, total hip) measured by DXA. The upper QUS SI cut-off \((SI > 78)\) identified in this study was also reported by Hans and Krieg (2009) using the same device. Using the 91.6% specificity cut-off in this study \((SI < 65)\), women would be more than seven times as likely to have osteoporosis at the femoral neck. Choosing an SI cut-off of 56, closer to the lower cut-off proposed by Hans and Krieg, would yield a 99.4% specificity and accordingly, would substantially increase the likelihood of women having osteoporosis given a positive test result by nearly 21 times. Other authors have reported much lower T-score cut-offs to reach 90% sensitivity and specificity, which may be due to small sample sizes, varying age groups, and/or BMD site measured (Edelmann-Schafer, et al., 2011; Gudmundsdottir, et al., 2005; Pearson, et al., 2003). Identifying QUS cut-offs based on best balance of sensitivity and specificity close to 90% yielded false-negative rates (25% to 35.7%) that were too high for clinical use at either DXA measurement site.

In this study, the cut-off method stipulated in previous OST validation cohorts yielded a sensitivity of 87.5% and corresponding cut-off < 2 with respect to T-score \(\leq -2.5\) at the femoral neck. These results indicate that at a recommended cut-off < 2, clinicians could identify close to 90% of women with osteoporosis at the femoral neck while excluding more than half of women (62.7%) with normal BMD. OST yielding the best balance between sensitivity and specificity achieved the same cut-off (< 2) at the femoral neck and lumbar spine in women. Similar to the results of this study, generally a
positive OST outcome with cut-off < 2 has been defined to detect 90% of postmenopausal women with low femoral neck BMD (sensitivity of 88% to 92%) at the expense of higher false-positive rates (29%-63%) to ensure that within a clinical setting, there is a high true positive rate (Geusens, et al., 2002; Richy, Gourlay, et al., 2004; Rud, et al., 2005).

Observing the LR of 0.20, at the chosen cut-off, indicates OST may be effective in ruling out osteoporosis at the femoral neck, however not at the lumbar spine (LR- 0.60), which required a higher cut-off (< 5) to achieve 90% sensitivity. A meta-analysis of postmenopausal women also showed the performance of OST in ruling out femoral neck T-score ≤ -2.5 was moderate in Caucasian women (sLR- 0.19) and poor at the lumbar spine (sLR- 0.43) (Rud, et al., 2007). Notably, the review included 18 studies of 60,774 Caucasian postmenopausal women of which the majority had low methodological quality. The authors highlighted the need for prospective research in a clinically representative sample, and methods in accordance with Standards for Reporting of Diagnostic Accuracy (STARD) protocol before recommended use of OST in a community-based or primary care setting. These methodological issues were respectively addressed in this study and given the results OST may be considered a useful pre-screening test for ruling out osteoporosis at the femoral neck.

Based on the results of this study and current Canadian clinical practice guidelines for treatment and fracture risk assessment, cut-offs should take into consideration DXA measurement site. Ideally, device-specific calcaneal QUS cut-offs should also be gender, age, and ethnicity dependent if they are to be used in pre-screening or diagnosis of osteoporosis (Gudmundsdottir, et al., 2005; Hans & Krieg, 2009). OST has already been
validated in Caucasian and Asian postmenopausal women, and studies have suggested performance of OST differs between women over and under 65 years of age (Gourlay, et al., 2005). This study involved a primarily Caucasian population (96%), stratified by gender. Based on the variability of the ROC curves for QUS and OST in men, it was not possible to establish optimal cut-off points that best differentiate those at high and low risk of osteoporosis. Also, although not assessed in this study, stratifying participants according to age groups (e.g., 50-64 years and 65-plus years) may have also affected sensitivity and specificity outcomes. For example, while the 90% specificity QUS cut-off in this study (SI < 65) was marginally higher than that suggested by Hans and Krieg (SI < 57) it is important to note this study included a much smaller and younger sample of women by comparison (n = 174, M age = 59 years vs. n = 5,954, ages 75 and older).

Overall, increasing prevalence of osteoporosis at both BMD sites with decreasing QUS and OST cut-off values was apparent. While lower (90% specificity) cut-offs were similar at the femoral neck and lumbar spine, based on LR+, QUS was more likely to detect osteoporosis at the femoral neck (LR+ 7.44) compared to the lumbar spine (LR+ 4.06). At 90% sensitivity, OST was less likely yielded a higher LR- (0.60) at the lumbar spine compared the femoral neck. Additionally, much higher upper (90% sensitivity) QUS and OST cut-offs (SI > 104, T-score > 0.25, OST < 5) were required to rule-out osteoporosis at the lumbar spine compared to the femoral neck. These results may reflect differences in bone strength, a composite of bone density and quality, at the various measurement sites (femoral neck, lumbar spine, calcaneus) (NIH, 2001). Notably, the average BMD T-scores were slightly higher at the lumbar spine (T-score = -0.6) compared to the femoral neck (T-score = -1.0) and BMD measurement made at the
femoral neck with DXA is used as the reference standard for fracture risk assessment (Papaioannou, et al., 2010).

5.5.1 Strengths and Limitations

This study sought to evaluate the diagnostic performance of QUS and OST while addressing methodological short-comings and/or limitations of previous studies. To our knowledge, this was the first study to collect data for the purpose of comparing the accuracy of two screening tests, the Achilles Lunar calcaneal QUS and a questionnaire-based screening test, OST, in a clinically-representative, stratified sample of men and women over 50 years of age in relation to DXA. Methodological strengths included consecutive recruitment of patients from the local hospital who were referred for DXA screening in order to reduce selection bias and to provide a realistic population of those attending a primary care setting for diagnostic screening. Furthermore, all DXA measurements were performed by the same trained technician, all QUS and OST measurements were performed by the same researcher, and the same DXA and QUS devices were used throughout the study. Therefore, the accuracy and precision of the measurements are considered high and consistent. As previously noted, the study population was stratified by gender and region of BMD assessed by DXA (femoral neck vs. lumbar spine), which allowed for more defined QUS and OST cut-offs.

Few studies have identified optimal QUS cut-offs based on ISCD recommendations. Studies that have proposed QUS cut-offs for detecting low BMD varied in study population (gender, age group, and ethnicity), study design, QUS device used, and BMD region of interest (Collinge, et al., 2010; Cook, et al., 2005; Pearson, et al., 2003). Results derived from this study were device-specific, so while they cannot be
applied to other QUS devices, they add to the evidence of the diagnostic performance of
the Achilles Lunar ultrasound and proposed cut-offs. While several studies have
identified cut-offs using OST, they primarily assess women. Based on implications for
future research suggested by Rud et al. (2007; 2009) in a recent meta-analyses of OST
and QUS, the present study placed emphasis on addressing the methodological short-
comings by following the Standards for Reporting of Diagnostic Accuracy (STARD)
guidelines for protocol and reporting (Bossuyt, et al., 2003), including reporting
participant characteristics, withdrawals, missing data, and uninterpretable test results.

There are also limitations that should be considered when interpreting results of
this study. First, the study population of women only was relatively small; however, for
QUS and OST results are generally in agreement with those of larger cohort studies of
older women (Geusens, et al., 2002; Hans & Krieg, 2009; Richy, Gourlay, et al., 2004).
The higher specificity cut-off for QUS compared to that reported by Hans and Krieg
likely reflects the younger mean age of women in this study. Also, as previously
discussed, the small sample size of men limits the generalizability of these results to a
wider population of men over 50 years of age. Second, this study included primarily
Caucasian participants; thus, a replication of this study with other ethnic groups would be
useful to provide evidence that QUS and OST are reliable pre-screening tests. Third, all
participants were referred for DXA screening by their HCP, a selection process that
should be based on clinical practice guidelines (Papaioannou, et al., 2010). Nonetheless,
prevalence of osteoporosis was low, which may be due to the study population including
only first-time screeners of which 76% were 50 to 64 years of age. Not only may this
explain the high number of normal BMDs compared to other studies, but it may have
prevented the QUS and OST from showing adequate sensitivity and specificity. Therefore, results from ROC analysis were carefully explained. Last, although this study collected data on fracture history of participants, the ability of QUS and OST to predict fracture was not assessed.

5.6 Conclusion

This study provided valuable insights to the comparative performance of QUS and OST in older women. Overall, the ability of QUS to identify women with osteoporosis at the femoral neck consistently out-performed QUS at the lumbar spine and OST at both the femoral neck and lumbar spine in men and women. Comparing the ROC curves in women alone, at the femoral neck it was evident that both QUS and OST had statistically significantly strong discriminatory ability, with QUS superior to OST. QUS proved to be an effective screening test for identifying older women with osteoporosis at the femoral neck with a lower SI cut-off of < 65 and an upper cut-off of > 78 to identify individuals who have high or low likelihood of osteoporosis. QUS SI values that fall between these lower and upper cut-offs would warrant DXA screening, as recommended by the ISCD. Given the high specificity and LR+, the lower cut-off may also warrant its use as a valuable osteoporosis screening device in lieu of DXA, for example in rural areas where access to DXA screening is limited. While studies suggest this device may be preferable in males also, the results from this study were inconclusive. For OST, a cut-off < 2 identified almost 90% of women with osteoporosis at the femoral neck. Overall, despite its simplicity, OST had lower diagnostic accuracy compared to QUS and given that the chosen cut-off would miss some cases (12.5%) and at the expense of higher false-positive rates, QUS may play a more valuable role in pre-screening. Notably, diagnostic
accuracy of QUS and OST was much higher at the femoral neck region, and their utility as pre-screening tests becomes more apparent when taking into account the beneficial effect of drug treatment demonstrated in women with low BMD at the femoral neck and the use of femoral neck BMD in fracture risk assessment. Further prospective research is needed to examine the gender-related differences of QUS and OST diagnostic performance, as current literature has mainly focused on women. In addition, research in non-Caucasian populations stratifying by age group will help to further define and establish appropriate cut-offs.
CHAPTER 6: STUDY 3
6.1 Introduction

Osteoporosis is a skeletal disease characterized by microarchitectural deterioration of the bone resulting in increased bone porosity and consequent susceptibility to fracture (Papaioannou, et al., 2010). It is estimated that over 2 million Canadians have osteoporosis, of which one in four are women and one in eight are men over 50 years of age. Additionally, 46% of postmenopausal women and 40% of men over 50 years of age are estimated to have osteopenia and are therefore at increased risk of developing osteoporosis (Tenenhouse, et al., 2000).

Osteoporotic fractures are associated with low bone mineral density (BMD) and most commonly occur at the hip, spine, and wrist (Warriner, et al., 2011). Over 80% of fractures in individuals 50 years of age and older are caused by osteoporosis, with estimates that one in three women and one in five men will experience an osteoporotic fracture during their remaining lifetime (Cummings & Melton, 2002). Due to the unprecedented increase in the population of older adults and the marked acceleration of bone loss with age, the risk of osteoporosis and number of related fractures is projected to rise. This poses a considerable financial burden in Canada, in addition to medical and social consequences.

Maintaining bone health requires an integrated approach to prevention and management of osteoporosis and its related fractures. This approach, as outlined in the Canadian clinical practice guidelines, requires timely DXA screening for those at risk, preventive health behaviour modification in men and women over age 50, and/or appropriate drug treatment based on fracture risk (Papaioannou, et al., 2010). The most common modifiable health behaviours encouraged for prevention and management
include adequate daily calcium and vitamin D intake (1,200 mg and 800 to 2,000 IU, respectively) and regular physical activity. The beneficial effects of these health behaviours on osteoporosis and fracture risk reduction are well-documented in several meta-analyses (Boonen, et al., 2007; Howe, et al., 2011; Prentice, et al., 2012; Tang, et al., 2007). In addition, there is consistent evidence that drug treatment options available in Canada, including both antiresorptive agents and bone-forming agents, are effective in reducing risk of fracture in men and women with osteoporosis (MacLean, et al., 2008; Murad, et al., 2012). However, despite the consequences of osteoporosis, practice guidelines, and well-established evidence supporting the efficacy and effectiveness of these preventive and management strategies, management of the disease is less than optimal. For example, even amongst high-risk men and women with fracture, less than 30% are subsequently diagnosed with osteoporosis and less than 20% of women and only 10% of men receive treatment (Giangregorio, et al., 2006; Papaioannou, et al., 2004; Papaioannou, et al., 2008). Additionally, Canadian national data shows older men and women are not meeting adequate total calcium and vitamin D intake levels (diet and supplement), and approximately 60% of older adults are physically inactive (Poliquin, et al., 2009; Vatanparast, et al., 2009; Warburton, et al., 2007). These findings highlight large gaps not only in care between best practice and actual care delivery, but also in knowledge about osteoporosis and preventive health behaviours among patients.

The current diagnostic criteria for osteoporosis, defined by the World Health Organization (WHO), are based on measurement of BMD by dual energy x-ray absorptiometry (DXA) (WHO, 1994). Recently revised practice guidelines in Canada, recommend all men and women over 65 years of age receive DXA screening, and those
50 to 64 years of age be routinely screened for osteoporosis risk factors (e.g., fragility fracture after age 40, rheumatoid arthritis) to identify those at high risk who should undergo DXA screening (Papaioannou, et al., 2010). Despite these practice guidelines, minority of Canadians are referred for DXA screening, contributing to the challenge of preventing and managing the disease, and identifying individuals who may benefit from treatment.

When combined with timely, thorough follow-up, DXA screening results provide important information about individual risk of osteoporosis. They are a critical and initial component of practice protocol for osteoporosis risk reduction informing clinical decisions and recommendations for prevention and management, in addition to patient health behaviour change. Consequently, if individuals are being screened, but unaware of their results, they may be less likely to engage in health behaviours to prevent and manage the disease. Research literature assessing the influence of DXA screening results on men and women’s decisions to engage in preventive health behaviours and/or treatment is limited. Rubin and Cummings (1992) found women (N = 261, $M_{age} = 59$ years, age range: 23-96 years) were more likely to start or increase calcium and vitamin D supplements, and exercise if their DXA screening results indicated low BMD compared to those with normal BMD results. However, this study did not assess change in health behaviours. Two studies assessing change in post-menopausal women’s calcium intake post-screening, found those with osteopenia or osteoporosis significantly increased calcium supplement intake or total calcium intake (diet and supplement) (McLeod, et al., 2007; Rohr, et al., 2006). Additionally, McLeod, McCann, Horvath, and Wactawski-Wende (2007) found both osteopenia and osteoporosis diagnosis were strong independent
predictors of women’s decision to change total calcium intake after taking into consideration confounding factors. In studies evaluating men, only one assessed change in calcium intake and exercise ($N = 196, M_{\text{age}} = 65.9$ years), showing those with osteopenia and osteoporosis increased total calcium intake, but not exercise, post-screening (Doheny, et al., 2010). Results of these studies, as well as others, were largely based on self-report or there was little detail on the measurement method. Also, majority of these studies are community-based (e.g., recruitment from churches, senior centres, etc.) and thus, may not capture samples representative of the population at risk for osteoporosis. Notably, no studies in the literature have evaluated the influence of DXA screening results on change in vitamin D intake. In addition, few studies evaluated confounding factors associated with behaviour change (Brennan, et al., 2004; McLeod, et al., 2007).

Regarding treatment, it has been shown that HCPs recommend and women initiate drug treatment more often when DXA screening results indicate increased risk of fracture (Brennan, et al., 2004; Cranney, et al., 2009; Fitt, et al., 2001; Rubin & Cummings, 1992). However, this research has been primarily limited to retrospective studies assessing women only (Brennan, et al., 2004; Cranney, et al., 2009; Fitt, et al., 2001; Rubin & Cummings, 1992). There is also limited assessment of other factors that may influence treatment initiation (e.g., fracture history, length of relationship with HCP, and gender of HCP) particularly from a Canadian perspective where universal health care and provincial drug benefit plans enable greater access. It is worthwhile to assess calcium and vitamin D intake, physical activity, and drug treatment initiation to understand the full influence of DXA screening on change in these health behaviours.
Diagnostic screening may be the first step in improving the osteoporosis care gap; however, there is also a traditional lack of knowledge and awareness about the disease among older men and women. Combined with DXA screening, increased knowledge and awareness about osteoporosis may help older adults make informed decisions about health behaviours for the prevention and management of the disease beyond that of DXA screening alone. Thus, there is a crucial need to address primary prevention of osteoporosis as it relates to health promotion of modifiable health behaviours in this population. Studies suggest that theory-informed education interventions are more effective in changing health behaviour in research and practice than those without (Glanz, et al., 2008; Grol, et al., 2007). Additionally, a recent meta-analysis suggests behaviour change interventions that are tailored on theoretical constructs in addition to demographics (e.g., age, gender) or behaviour (e.g., calcium supplement use, exercise) are more effective than those based on behaviour or theory alone (Noar, et al., 2007). Despite this understanding, the use of theory in osteoporosis education interventions is largely underutilized and lacks specification in research literature.

The Health Belief Model and Theory of Self-Efficacy are the most widely applied conceptual frameworks for explaining and predicting osteoporosis preventive health behaviours and their relationship to health beliefs and experiences (Bandura, 1977; Kim, et al., 1991; McLeod & Johnson, 2011; I. Rosenstock, 1966). These two models have been combined to a single model called the Revised Health Belief Model (RHBM) (I. Rosenstock, et al., 1988). The underlying premise of the RHBM is that individuals will be more likely to engage in preventive health behaviour if they perceive the disease as a threat, perceive greater benefits than barriers towards taking preventive action against the
disease, and believe in their ability to successfully carry out the preventive behaviour. Osteoporosis education intervention studies using theory, and in particular, the RHBM as a guiding framework are limited and vary in study population and design, method of education intervention, and length of follow-up (Babatunde, et al., 2011; Sedlak, et al., 2000; Tusssing & Chapman-Novakofski, 2005). For example, a recent experimental study showed the delivery of six weekly, RHBM-based group education sessions improved dietary calcium intake in African-American men (n = 11) and women (n = 99) over 50 years of age. However, other health behaviour outcomes were not assessed and it was unknown whether men and women had ever undergone BMD screening (Babatunde, et al., 2011). In contrast, Sedlak, Doheny, and Jones (2000) found no significant change in calcium intake and weight-bearing exercise after RHBM-based education, regardless of the length and method of education presentation. Notably, non-randomized convenience samples of women ranging in age from 22 to 83 years were examined.

An osteoporosis prevention and management strategy that includes both timely DXA screening and theory-informed education has the potential to increase health behaviour change beyond that of DXA screening or education alone. From a practical, public health perspective this education intervention would target at-risk men and women, increase awareness about the disease and target key RHBM constructs for behaviour change. When combined with DXA screening results, this primary and secondary prevention approach to improving the care gap would have potential long-term cost-saving benefits for the health care system when compared to the costs of treating and caring for individuals who have already developed osteoporosis or experienced osteoporotic fracture.
Only one study has examined the effects of a theory-based education intervention combined with DXA screening on health behaviour outcomes. Using tailored interventions, Sedlak, Doheny, Estok, and Zeller (2005) found postmenopausal women (age range 50 to 65 years) in both the tailored \((n = 23)\), and non-tailored \((n = 101)\), groups significantly increased calcium intake \((p < 0.008 \text{ and } p < 0.001, \text{ respectively})\) and there was no significant difference between groups. Weight-bearing exercise behaviours significantly decreased in the tailored intervention group and there was small, but non-significant increase in the non-tailored group. These findings suggest that osteoporosis screening alone may be more effective in changing health beliefs and behaviours than combined screening and theory-informed education. However, there were methodological shortcomings of the study affecting its quality and interpretation of results, including unequal sample sizes, and lack of validated instruments used to determine calcium intake and exercise.

The purpose of this experimental study was to determine the influence of DXA screening combined with tailored, theory-informed osteoporosis education versus usual care (DXA screening alone) on change in health behaviours of men and women over 50 years of age with no prior knowledge of their bone density. Specifically, health behaviour outcomes assessed included, total calcium and vitamin D intake (diet and supplement), physical activity, and drug treatment initiation. A further aim was to determine the independent factors influencing behaviour change.
6.2 Methods

6.2.1 Setting and Study Population

This population-based research was completed in Regina, Saskatchewan, Canada (population 210,000) between July 2010 and March 2012. A 6-month randomized controlled trial of a multifaceted, tailored, theory-informed osteoporosis education intervention and DXA screening or DXA screening alone was conducted in 203 men and women over 50 years of age who were referred to a local hospital for the first time to undergo DXA screening. Patients referred by their HCP for DXA screening at the Regina General Hospital over a 14-month period (July 2010 to September 2011) were considered for enrollment in the study. Referral for screening by HCPs was based on clinical risk factors and/or diagnostic judgment of the HCP. Participants were recruited through flyers placed in waiting areas throughout the Nuclear Medicine Department at the hospital. The DXA technician also played a critical role in the recruitment process by distributing letters of invitation to patients receiving DXA screening for the first time and completing postcards of those interested and agreeing to be contacted. The completed postcards included the patient’s name, phone number, and screening date and were collected weekly by the primary researcher for telephone follow-up. Interested patients were screened over the telephone and deemed eligible for inclusion in the study if they were 50 years of age and older, referred for DXA screening by their HCP, received screening for the first time, and were willing to sign a letter of informed consent. Excluding factors used to determine the final eligible study population included previous diagnosis and/or treatment for osteoporosis, having an unstable medical condition (respiratory, metabolic, or cardiovascular), receiving palliative care, or advanced cognitive impairment of any
kind that would preclude the participant from understanding the letter of information and signing the informed consent.

During the course of the study, 298 patients who underwent DXA screening were identified as potentially eligible for enrollment based on age and first-time screening. Of those potential participants, we were unable to contact 39, and 34 declined eligibility screening as they were not interested or unable to participate. Of the remaining 225 screening for eligibility, three were deemed ineligible due to osteoporosis treatment use or advanced cognitive impairment and 18 were unwilling to participate after scheduling for the following reasons: death in the family/personal reasons, too busy/no time, no longer interested/multiple unexcused cancellations, and too many questionnaires to complete. A total of 204 men and women were included in the study and provided informed consent, of which one was excluded from the analysis as DXA results were uninterpretable. The final study population included 203 men and women (176 women and 28 men, $M_{\text{age}} = 59.7$ years, age range: 50-80 years). The study was approved by the University of Regina Research Ethics Board and the Regina Qu’Appelle Health Region prior to participant recruitment and data collection.

6.2.2 Randomization

Eligible participants were consecutively, randomly assigned to an intervention group (education intervention) or a usual care group (no education) using a computerized generated randomization scheme (SPSS Statistics Version 17.0, Armonk, NY) (Figure 10). While there was no allocation concealment, allocations were implemented consecutively for each participant with no variation to the order in which participant numbers were assigned. Neither the participants nor the researcher were aware of DXA
screening results at the time of randomization and baseline measurements. While participants could not be blinded to the fact they were participating in a bone health study, they were unaware of their group assignment until the day of their baseline visit.

6.2.3 Education Intervention

The osteoporosis education intervention was administered at baseline. The RHBM provided the theoretical framework for development of the education. The curriculum was built on existing knowledge translation tools and resources developed by Osteoporosis Canada, and newly developed material encompassing the various RHBM constructs identified as important health beliefs in older men and women and/or associated with carrying out osteoporosis prevention and management health behaviours. These constructs include perceived seriousness, susceptibility, benefits, barriers, and self-efficacy of calcium intake and exercise (McLeod & Johnson, 2011). In addition to using a theory-based approach, the education intervention was unique in that it included: (a) a package of print material (e.g., fact sheets, brochure, facts and myths summary) that was reviewed one-on-one with the participant and also served to reinforce beliefs and behaviours after the intervention, (b) a 15-minute educational video titled, “Osteoporosis: Meeting the Challenges”, developed by Osteoporosis Canada that aimed to increase knowledge about osteoporosis and its risk factors, including personal testimonials from men and women with osteoporosis at various life-stages, (c) easy-to-read nutrition magnets, (d) an approach that was tailored to men versus women, and where applicable, content that was adapted to a local context (e.g., provided local opportunities and sites to engage in physical activity) and, (e) one-on-one sessions for administration rather than group sessions, allowing for open discussion and questions between the participant and
researcher. The education intervention took approximately 30 minutes to complete depending on participant questions.

6.2.4 Usual Care Group

Both groups (usual care and intervention) underwent DXA screening, baseline measures and six-month follow-up. The usual care group received the osteoporosis education package, including fact sheets, brochures, and magnet at follow-up.

6.2.5 Dual Energy X-ray Absorptiometry

All participants, regardless of group allocation underwent DXA screening prior to baseline. A trained and certified technician from the hospital measured BMD using the gold standard DXA (GE Lunar Prodigy, Madison, WI) at the lumbar spine (L1-L4), left, and right femoral neck. The same DXA machine was used for all participants. The lowest absolute value of BMD for all sites measured, specifically, T-scores and categorized T-scores as normal (T-score ≥ -1), osteopenia (T-score < -1.0 to > -2.5), or osteoporosis (T-score ≤ -2.5) based on WHO diagnostic criteria were used.

6.2.6 Procedure

6.2.6.1 Baseline

After DXA screening, participants attended the University of Regina for baseline assessment. Prior to their visit, they were mailed a packet containing a letter of information, letter of informed consent to read with instructions to be signed on the day of baseline visit, and three questionnaires to complete: the Background Health History Questionnaire, 3-Day Food Record, and the Modified Baecke Physical Activity Questionnaire for older adults. The packet also contained a map and directions to the lab, a parking permit, and a letter that thanked them for their interest with itemized
questionnaires enclosed in the packet, and explained what they were required to bring for their visit (e.g., completed questionnaires, and parking permit). At the beginning of baseline visit the participant’s returned questionnaires were reviewed for completion and missing information. The participant was asked to clarify or provide answers as needed. The participant was notified of his/her group allocation and completed another series of questionnaires related to osteoporosis health beliefs (not examined in this study). Breaking up questionnaire completion prior to- and during baseline visit was important to reduce questionnaire fatigue. After questionnaires were complete, anthropometric measures were taken including height and weight. Participants randomized to the intervention group received osteoporosis education at the end of all measurements.

6.2.6.2 Follow-up

Participants completed follow-up six months after baseline assessment. Three to four weeks prior to follow-up, participants were contacted to schedule a final visit. To optimize follow-up response rate, if participants were not contacted initially, a voicemail was left reminding them of the study, that their follow-up was soon approaching, and to kindly respond at their earliest convenience. If there was no response after two days, follow-up calls were made. Similar to recruitment, this method proved successful as retention rate for the study was high. Also, similar to baseline, they were mailed a follow-up packet containing a map, directions, and parking permit, a letter thanking them for their previous participation and the importance of their continued participation, a 3-Day Food Record, the Modified Baecke Physical Activity Questionnaire, and a Follow-up questionnaire assessing HCP recommendations since baseline and their DXA screening and health behaviour change. They were also asked to report any calcium, vitamin D
and/or multivitamin supplements they were currently taking, including brand name amount. They were instructed to complete the enclosed questionnaires and bring the completed questionnaires to their follow-up visit. At follow-up, questionnaires were checked for completion, and participants completed a series of osteoporosis health beliefs (not examined in this study), and anthropometric measures. Follow-up visits lasted 30 minutes. All measurements and contact with participants were carried out by the same researcher.

6.2.7 Outcome Measures

The battery of questionnaires at baseline and follow-up were used to measure four primary outcomes of interest: start or increase in calcium and vitamin D intake, physical activity, and osteoporosis drug treatment initiation.

6.2.7.1 Background Health History Questionnaire

The baseline background questionnaire was designed to obtain personal socio-demographic information (e.g., education, employment, marital status, and income) as well as information regarding the participants’ health histories, and known risk factors for osteoporosis (e.g., personal medical history including fracture history, family history of fracture, routine consumption of calcium-fortified foods, smoking, alcohol, and caffeine consumption, and general physical activity habits). Questions about routine medical care included number of visits with their primary HCP in the past five years, their gender, as well as current and past medication and supplement use in the last 30 days. Dosages and duration of use of medication and supplements were recorded.
6.2.7.2 3-Day Food Record

Change in calcium and vitamin D intake (dietary and supplement) was assessed by comparisons at baseline and follow-up. Specifically, the 3-Day Food Record was used to assess calcium and vitamin D intake from food and beverage consumed for three typical days, including two weekdays and one weekend day. The participant recorded the meal, time and place of consumption, specific foods and beverages consumed, how it was prepared, and the serving size. This provided an accurate description of the participant’s typical diet in order to analyze dietary calcium (mg/day) and vitamin D (IU/day) intake. The 3-day food record provided detailed and explicit instructions for completion, including tips for estimating serving size, reminders to include condiments and beverages including alcohol, as well as an example food record to follow.

6.2.7.3 Modified Baecke Physical Activity Questionnaire

Change in physical activity was assessed using the Modified Baecke Physical Activity Questionnaire (Voorrips, Ravelli, Dongelmans, Duerenberg, & Staveren, 1991) self-administered at baseline and follow-up. The questionnaire evaluates habitual physical activity, specifically household activities, sport, and leisure time activities over the past year. Ten questions pertaining to household activities, particularly household work, meal preparation, number of stairs walked per day and the frequency of excursions from the home had four to five possible answers, classifying the activity from inactive to very active. Questions about sport and leisure time activities included the type of activity, intensity of the activity, frequency of performance, and the number of months per year the activity was performed. Codes were recorded reflecting intensity, time, and months per year spent performing the activity. The participant listed up to two sport activities and
six leisure time activities in which they regularly partook. A total activity score was determined by summing the household score, sport score, and leisure time activity score yielding a continuous overall unitless activity score. For descriptive purposes, participants were classified as high (physical activity score ≥ 16.5), moderate (physical activity score > 9.4 and < 16.5), or low (physical activity score ≤ 9.4) level physical activity. An increase in the total mean activity score from baseline to follow-up was used to indicate change in physical activity.

To prevent and manage osteoporosis, Osteoporosis Canada recommends a comprehensive physical activity program that includes: weight-bearing exercise, strength training exercise, posture training, balance and stretching exercises (Osteoporosis Canada, 2012). The Modified Baecke Physical Activity Questionnaire assesses habitual physical activity, and thus the variety of exercises and daily activities that encompass those recommended by Osteoporosis Canada, particularly in older adults.

6.2.7.4 Anthropometric Assessments

Wearing a bathing suit (women) or shirtless and compression shorts (men), participants’ body weight was measured at both baseline and follow-up visits using a calibrated digital scale to the nearest 0.01 kg. Height was measured at baseline and determined using a portable stadiometer with weighing scale and measured to the nearest centimeter.

6.2.7.5 Follow-Up Questionnaire

Osteoporosis drug treatment initiation six months following baseline was assessed based on self-report questions in the Follow-up Questionnaire. The follow-up questionnaire consisted of questions assessing health behaviour change in the six months
following baseline. Follow-up questions addressed routine medical care of participants, whether participants discussed DXA screening results with their HCP, whether their HCP recommended calcium or vitamin D intake, physical activity, or prescribed osteoporosis drug treatment, whether participants initiated the recommendations, and whether they were currently maintaining the health behaviours. Participants were also asked to report on their personal decisions to make any health behaviour changes that were not recommended by their HCP and whether these changes were being maintained. Last, if they were currently taking calcium, vitamin D and/or multivitamin supplement, they were asked to report the brand name, amount, and amount taken daily.

6.3 Study Power

A priori power analysis was calculated by G*Power 3.1 software (Faul, Erdfelder, Lang, & Buchner, 2007) based on statistical power of 0.80, a minimum effect size of 0.20, two-tailed alpha of 0.05, and assuming a loss to follow-up of 10%, a sample size of 200 participants was necessary. To ensure adequate study power when using logistic regression analyses, the recommended minimum sample size ranges from five to 10 cases per independent variable (Kleinbaum & Klein, 2002). Regression model diagnostics and univariate analyses allowed for careful consideration of variables, thus reducing the potential to find statistical significance by chance alone, which may have occurred otherwise by including all independent variables in the regression model without effort to include only those with contextual plausibility.

6.4 Statistical Analysis

Statistical analyses were completed using the Statistical Package for the Social Sciences (SPSS, version 17.0). Descriptive statistics were computed for participant
characteristics including demographic variables and risk factors for osteoporosis, as well as DXA T-score level (lowest of three sites reported), calcium and vitamin D dietary and supplement intake (mg/day, and IU/day, respectively), physical activity, and routine medical care and medication use. Continuous variables were expressed as means and standard deviations. Categorical variables were summarized as counts and proportions. Student’s $t$-test and chi-square were used for comparisons of means and proportions, respectively. Paired $t$-tests were performed to test for statistically significant differences in calcium and vitamin D intake and physical activity within groups (usual care and intervention) from baseline to 6-month follow-up. Differences in calcium and vitamin D intake, physical activity, and drug treatment initiation between groups (usual care vs intervention) at 6-month follow-up were examined using independent $t$-tests and chi-square. The level of statistical significance was set at $p \leq .05$. To determine factors associated with change in these health behaviours, univariate and multivariate logistic regression models were built.

6.4.1 Logistic Regression Model Diagnostics

To inform the multivariate model building, preliminary analyses were conducted. Regression model diagnostics provide confirmation that assumptions of logistic regression are met. This includes examining the frequency of categorical variables and the distribution of continuous variables in relation to the dependent variables (primary outcomes of interest) used. Logistic regression analysis requires at least one case be present between each categorical variable and the dichotomous outcome variable, and it is best that no more than 20% of cases are less than five (Tabachnick & Fidell, 2007). A zero cell is particularly problematic as it yields a point estimate of either zero or infinity.
for the odds ratio of the variable in question in the regression model (Tabachnick & Fidell, 2007). Contingency tables were examined for each categorical variable versus the dichotomous outcome variable to determine if any table resulted in a zero cell for which variables with zero cells would be excluded from the regression analyses. Analysis revealed all cells had at least one case present.

Logistic regression also assumes a linear relationship between continuous predictors (independent variables) and the outcome of interest (Tabachnick & Fidell, 2007). Including influential variables biases coefficient estimates and may result in large standard errors, and lead to invalid statistical inferences. Histograms and box-and-whisker plots were plotted to examine data distribution, specifically kurtosis, skewness, and whether outliers were present for all continuous variables (calcium and vitamin D intake, age, body weight, number of current medications and physical activity score). The histogram and box-and-whisker plots indicated mild skewness in the data, but no presence of major outliers.

Correlations between independent variables were also examined to ensure absence of multicollinearity in the final logistic regression model. High correlation between two or more predictor variables is signaled by very large standard errors and thus increased type II error (Tabachnick & Fidell, 2007). To assess for multicollinearity, correlation coefficients were calculated between independent variables (Table 13).
Table 13

Correlation Coefficients

<table>
<thead>
<tr>
<th>Measure of Independent Variable</th>
<th>Continuous</th>
<th>Categorical</th>
<th>Dichotomous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous</td>
<td>Pearson</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Categorical</td>
<td>Polyserial</td>
<td>Phi</td>
<td></td>
</tr>
<tr>
<td>Dichotomous</td>
<td>Point-Biserial</td>
<td>Polychoric</td>
<td>Tetrachoric</td>
</tr>
</tbody>
</table>

Any pair of variables found to have a correlation of 0.8 or greater (considered high correlation) was flagged and only one variable of the pair was included in the multivariable model (Moore, McCabe, & Craig, 2007). Decisions were made regarding which variable to include based on the variable’s relevance to the outcome of interest. Results of this analysis showed a large correlation between total calcium intake at baseline (mg) and calcium supplement intake at baseline (mg) \((r = .821)\), and total calcium intake at baseline (mg) and total calcium intake at baseline (<1,200 and ≥1,200 mg/day) \((r = .820)\). It was therefore, important to include only one of the three variables in the multivariable regression model. The variable total calcium intake (<1,200 and ≥1,200 mg/day) was retained as it takes into consideration both supplement and dietary intake at baseline. In addition, it reduces redundancy of including the same variable in both continuous and categorical forms.

A large correlation between total vitamin D intake at baseline (IU) and vitamin D supplement intake at baseline (IU) \((r = .866)\) was also found. Thus, the variable total vitamin D intake (IU) was retained as it takes into consideration both supplement and dietary intake at baseline. Correlations between 0.5 and 0.8 were considered moderate.
correlations and pairs of variables with correlation coefficients approaching 0.8 were also flagged and examined further. A correlation coefficient of 0.77 was found between total vitamin D intake at baseline (IU) and total vitamin D intake at baseline (< 800 and ≥ 800 IU/day). Similar to calcium, the continuous total vitamin D variable was removed and categorical variable retained to limit redundancy of including the same variable in different forms.

6.4.1.1 Univariate Logistic Regression Analyses

Univariate logistic regression was performed to determine the association between independent variables and the four outcomes of interest (change in calcium intake, change in vitamin D intake, change in physical activity, and drug treatment initiation) and to identify variables considered for use in the multivariate regression model. The dependent variables were modeled from questions in the follow-up questionnaire (drug treatment initiation) and change in calcium and vitamin D intake (dietary and supplement) and physical activity were assessed by comparisons at baseline and follow-up (3-Day Food Record for dietary calcium and vitamin D intake, Background Health History Questionnaire for reported calcium and vitamin D supplement intake, Modified Baecke Physical Activity Questionnaire for physical activity, and Follow-Up Questionnaire for reported calcium and vitamin D supplement intake).

Primary independent variables assessed for all outcomes of interest included DXA screening results reported as T-score level based on WHO definitions (normal, osteopenia, osteoporosis) and theory-based osteoporosis education intervention (yes or no). These variables were included in both univariate and multivariate logistic regression
analyses regardless of \( p \)-value, and retained. The potential confounding variables (secondary independent variables) from the baseline data and follow-up data used in the analysis were chosen a priori based on thoughtful consideration of demographic variables (e.g., age, gender, income, etc.), health motivation (e.g., discussion of DXA screening results with HCP), risk factors associated with osteoporosis (e.g., calcium and vitamin D intake, smoking, family history of fracture, etc.), and previous research literature citing factors associated with these lifestyle behaviours (e.g., gender of HCP). Prior to univariate analyses these variables underwent regression model diagnostic evaluation as described above to identify and eliminate redundant variables. Univariate regression analyses were then performed to examine the association between each independent variable and the dependent variables and to determine which variables would be used in multivariate analysis.

6.4.1.2 Multivariate Logistic Regression Analyses

Multivariate logistic regression analyses were conducted to determine independent predictors of change in calcium intake, vitamin D intake, and physical activity, and initiation of drug treatment. All factors associated (\( p < .25 \)) with the outcomes of interest in univariate analyses were considered in the multivariate logistic regression models. To yield the best predictive multivariate model, a \( p \)-value < .25 is considered an appropriate cut-off value for considering variables into a multivariate regression analysis (Mickey & Greenland, 1989). To establish the final predictive model, a backward stepwise approach was performed with variables statistically significant at \( p < 0.05 \) retained. Regardless, of statistical significance, the primary independent variables of interest were forced into the model because of their importance in either the design of
the study, previous observations of their effects on the outcomes of interest, or both. The level of statistical significance was set at $p \leq .05$. 
Figure 10. Flow diagram of study participants through the trial.
6.5 Results

Figure 10 shows the trial profile. Between July 2010 and September 2011, 203 men and women over 50 years of age were randomly allocated to a usual care group \( (n = 101) \) or intervention group \( (n = 102) \). Of the 203 men and women participating in the study, 92.1% completed 6-month follow-up. Fifteen participants withdrew from the study, of whom majority were lost to follow-up and one withdrew due to adverse events.

Table 14 summarizes participant demographics, osteoporosis risk factors, and the distribution of BMD at baseline by group. Ninety-six percent of men and women were Caucasian, with the remaining 4% of Asian, First Nations or Métis decent. The total mean age of participants was 59.7 ± 7.1 (age range 50-80 years), including 28 men and 175 women. Majority of participants were 50 to 64 years of age (75.4%), married or common-law (77.8%), highly educated (58.6%), had a family history of fracture (53.0%), sought routine medical care more often than once yearly (78.8%), and had low physical activity levels (51.7%). Of the 175 women, 88% were post-menopause.

Results of DXA screening showed 39.4% of men and women had normal BMD, 49.3% had osteopenia, and 11.3% were newly diagnosed with osteoporosis based on WHO criteria. Participants’ mean total calcium intake (1,137 mg/day) and vitamin D intake (742 IU/day) were below recommended levels of 1,200 mg/day and >800 IU/day, respectively.

Comparison of groups at baseline showed participants in the intervention group were older (61.2 ± 7.5 years vs 58.4 ± 6.4 years), more likely to be married (86.3% vs 69.3%), and more likely to be moderately physically active according to categorized physical activity levels (45.0% vs 25.7%) compared to the usual care group \( (p < .05) \). However, mean physical activity scores were comparable between usual care and
intervention group (10.3 ± 5.8 vs 11.1 ± 5.7) (results not shown). For the purpose of this study, further analyses were conducted based on the continuous mean physical activity score. All remaining descriptive variables including gender, education level, income, DXA T-score level, fracture history (individual and family), routine medical care, and calcium and vitamin D intakes (diet, supplement, and total) were comparable in both groups and there were no significant differences.
## Table 14

*Baseline Characteristics of Participants by Group*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Usual Care (n = 101)</th>
<th>Intervention (n = 102)</th>
<th>Total (N = 203)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n or M (SD)</td>
<td>n or M (SD)</td>
<td>n or M (SD)</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-64 years</td>
<td>83 (82.2)</td>
<td>70 (68.6)*</td>
<td>153 (75.4)</td>
</tr>
<tr>
<td>65-80 years</td>
<td>18 (17.8)</td>
<td>32 (31.4)*</td>
<td>50 (24.6)</td>
</tr>
<tr>
<td>Body mass (kg)</td>
<td>74.1 (15.8)</td>
<td>75.3 (16.7)</td>
<td>74.7 (16.2)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12 (11.9)</td>
<td>16 (15.7)</td>
<td>28 (13.8)</td>
</tr>
<tr>
<td>Female</td>
<td>89 (88.1)</td>
<td>86 (84.3)</td>
<td>175 (86.2)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>10 (9.9)</td>
<td>4 (3.9)*</td>
<td>14 (6.9)</td>
</tr>
<tr>
<td>Married/common-law</td>
<td>70 (69.3)</td>
<td>88 (86.3)*</td>
<td>158 (77.8)</td>
</tr>
<tr>
<td>Divorced/widowed</td>
<td>21 (20.8)</td>
<td>10 (9.8)*</td>
<td>31 (15.3)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary/high-school</td>
<td>43 (42.6)</td>
<td>41 (40.2)</td>
<td>84 (41.4)</td>
</tr>
<tr>
<td>University/post-graduate</td>
<td>58 (57.4)</td>
<td>61 (59.8)</td>
<td>119 (58.6)</td>
</tr>
<tr>
<td>Income (&gt; $30,000)</td>
<td>86 (94.5)</td>
<td>64 (91.4)</td>
<td>150 (93.2)</td>
</tr>
</tbody>
</table>
Table 14 (continued)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Usual Care (n = 101)</th>
<th>Intervention (n = 102)</th>
<th>Total (n = 203)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n or M (SD)</td>
<td>%</td>
<td>n or M (SD)</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>62 (n = 101)</td>
<td>61.4%</td>
<td>62 (n = 102)</td>
</tr>
<tr>
<td>Past</td>
<td>39 (n = 101)</td>
<td>38.6%</td>
<td>40 (n = 102)</td>
</tr>
<tr>
<td>Current</td>
<td>10 (n = 101)</td>
<td>9.9%</td>
<td>10 (n = 102)</td>
</tr>
<tr>
<td></td>
<td>124 (n = 203)</td>
<td>61.1%</td>
<td>79 (n = 203)</td>
</tr>
<tr>
<td>Glucocorticoid use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>94 (n = 101)</td>
<td>93.1%</td>
<td>99 (n = 102)</td>
</tr>
<tr>
<td>Past/Current</td>
<td>7 (n = 101)</td>
<td>6.9%</td>
<td>3 (n = 102)</td>
</tr>
<tr>
<td></td>
<td>193 (n = 203)</td>
<td>95.1%</td>
<td>10 (n = 203)</td>
</tr>
<tr>
<td>Fracture after 40 years of age (yes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>24 (n = 101)</td>
<td>23.8%</td>
<td>21 (n = 102)</td>
</tr>
<tr>
<td></td>
<td>45 (n = 203)</td>
<td>22.3%</td>
<td></td>
</tr>
<tr>
<td>Family history of fracture (yes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>55 (n = 101)</td>
<td>54.5%</td>
<td>52 (n = 102)</td>
</tr>
<tr>
<td></td>
<td>107 (n = 203)</td>
<td>53.0%</td>
<td></td>
</tr>
<tr>
<td>DXA T-score level(^a)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>47 (n = 101)</td>
<td>42.5%</td>
<td>33 (n = 102)</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>41 (n = 101)</td>
<td>40.6%</td>
<td>59 (n = 102)</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>13 (n = 101)</td>
<td>12.9%</td>
<td>10 (n = 102)</td>
</tr>
<tr>
<td></td>
<td>80 (n = 203)</td>
<td>39.4%</td>
<td>100 (n = 203)</td>
</tr>
<tr>
<td>Routine medical care (more often than once yearly)</td>
<td>80 (n = 101)</td>
<td>79.2%</td>
<td>80 (n = 102)</td>
</tr>
<tr>
<td>Number of current medications</td>
<td>1.5 (1.3)</td>
<td></td>
<td>1.2 (1.2)</td>
</tr>
<tr>
<td></td>
<td>1.4 (1.3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 14 (continued)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Usual Care</th>
<th>Intervention</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( n = 101 )</td>
<td>( n = 102 )</td>
<td>( n = 203 )</td>
</tr>
<tr>
<td>Physical activity level</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>59 (59.4)</td>
<td>47 (46.1*)</td>
<td>105 (51.7)</td>
</tr>
<tr>
<td>Moderate</td>
<td>26 (25.7)</td>
<td>46 (45.0*)</td>
<td>72 (35.5)</td>
</tr>
<tr>
<td>High</td>
<td>16 (15.8)</td>
<td>9 (8.8*)</td>
<td>26 (12.8)</td>
</tr>
<tr>
<td>Dietary calcium intake (mg/day)</td>
<td>746 (296)</td>
<td>793 (300)</td>
<td>770 (298)</td>
</tr>
<tr>
<td>Calcium supplement intake (mg/day)</td>
<td>399 (423)</td>
<td>337 (419)</td>
<td>368 (421)</td>
</tr>
<tr>
<td>Total calcium intake (mg/day)</td>
<td>1,145 (536)</td>
<td>1,130 (510)</td>
<td>1,137 (522)</td>
</tr>
<tr>
<td>Dietary vitamin D intake (IU/day)</td>
<td>132 (145)</td>
<td>107 (91)</td>
<td>119 (121)</td>
</tr>
<tr>
<td>Vitamin D supplement intake (IU/day)</td>
<td>613 (636)</td>
<td>633 (632)</td>
<td>623 (632)</td>
</tr>
<tr>
<td>Total vitamin D intake (IU/day)</td>
<td>746 (653)</td>
<td>739 (620)</td>
<td>742 (635)</td>
</tr>
</tbody>
</table>

*Note. DXA = dual energy x-ray absorptiometry. IU = International Units.

\( ^a \) Lowest T-score for three sites measured by DXA (lumbar spine, right and left femoral neck). T-score level was based on WHO definitions for normal, osteopenia, and osteoporosis.

\( ^* \) \( p < .05 \) for \( t \)-test and chi-square comparing usual care and intervention at baseline.
As shown in Figure 10, 92.1% of participants (188 of 203) completed the study and retention rates for study completion were similar within the usual care (92.1%) and intervention group (93.1%). Table 15 shows 6-month changes in calcium and vitamin D intake (diet, supplement, and total intake), and physical activity for both groups. Participants in the intervention group statistically significantly increased calcium supplement intake from 354 mg to 785 mg, \( t(94) = -8.65, p < .01 \), and total calcium intake from 1,152 mg to 1,590 mg, \( t(94) = -7.95, p < .01 \). However, the usual care group also statistically significantly increased their calcium supplement intake from 409 mg to 561 mg, \( t(92) = -3.61, p < .01 \), and total calcium intake from 1,173 mg to 1,340 mg, \( t(92) = -3.11, p < .01 \). While there was a small increase in dietary calcium intake for both groups, it was not statistically significant.

Similar to calcium, vitamin D supplement intake increased in the intervention group from 663 IU to 1,210 IU, \( t(94) = -8.55, p < .01 \), and total vitamin D intake also increased from 773 IU to 1329 IU, \( t(94) = -8.63, p < .01 \). The usual care group also statistically significantly increased their vitamin D supplement intake from 640 IU to 965 IU, \( t(92) = -5.20, p < .01 \), and total vitamin D intake from 778 IU to 1,086 IU, \( t(92) = -4.89, p < .01 \). Changes in dietary vitamin D intake from baseline to follow-up for both groups were not statistically significant.

While it was anticipated the intervention would increase physical activity, there was a slight, but non-significant increase in mean activity scores from baseline (11.4) to follow-up (11.8), \( t(94) = -.69, p = .49 \). Activity scores in the usual care group decreased slightly from baseline to follow-up.
Table 15  

*Calcium and Vitamin D Intake and Physical Activity at Baseline and 6-month Follow-up By Group*

|                      | Usual Care (n = 93) |                          | Intervention (n = 95) |                          |          |          |          |          |
|----------------------|----------------------|--------------------------|-----------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
|                      | Baseline             | Follow-up                |                       | Baseline                 | Follow-up                | t(92)    | p         | Baseline             | Follow-up                | t(94)    | p         |
|                      | M        | SD   | M        | SD   | M        | SD   |          | M        | SD   |          | M        | SD   |
| Dietary calcium      | 764      | 300  | 779      | 314  | -52      | .60  |          | 798      | 302  | -34      | .73  |          |
| Calcium supplement   | 409      | 431  | 561      | 473  | -3.61    | <.01 |          | 354      | 425  | -8.65    | <.01 |          |
| Total calcium        | 1,173     | 540  | 1,340     | 544  | -3.11    | <.01 |          | 1,152     | 515  | -7.95    | <.01 |          |
| Dietary vitamin D    | 138      | 149  | 125      | 132  | 1.25     | .21  |          | 111      | 93   | -62      | .53  |          |
| Vitamin D supplement | 640      | 645  | 965      | 783  | -5.20    | <.01 |          | 663      | 638  | -8.55    | <.01 |          |
| Total vitamin D      | 778      | 658  | 1,086     | 780  | -4.89    | <.01 |          | 773      | 622  | -8.63    | <.01 |          |
| Physical activity    | 10.4     | 5.8  | 10.1      | 5.5  | .52      | .60  |          | 11.4      | 5.8  | 11.8     | 6.1  | -.69     | .49  |          |

*Note.* Calcium units are mg/day. Vitamin D units are IU/day. Physical activity based on mean score. Total calcium and vitamin D intake = diet and supplement.
To determine differences between the usual care group and intervention group for calcium and vitamin D intake, physical activity, and drug treatment initiation, independent t-tests and chi-square (Fisher’s exact test) were calculated (Table 16). There was a statistically significant difference in calcium supplement intake ($M = 785\ mg, SD = 491$), $t(186) = -3.19, p < .01$, and total calcium intake ($M = 1,590\ mg, SD = 610$), $t(186) = -2.97, p = .03$, in the intervention group compared to the usual care group ($M = 561\ mg, SD = 473$ and $M = 1,340\ mg, SD = 544$, respectively). No statistically significant differences were found for dietary calcium intake between groups.

Similar to calcium, participants in the intervention group had significantly higher vitamin D supplement intake ($M = 1,210\ IU, SD = 777$), $t(186) = -2.15, p = .03$ and total vitamin D intake ($M = 1,329\ IU, SD = 778$), $t(186) = -2.13, p = .03$ at follow-up compared to those in the usual care group ($M = 965\ IU, SD = 783$ and $M = 1,086\ IU, SD = 780$, respectively). Again, no statistically significant differences were found for dietary vitamin D intake between groups.

With respect to physical activity, there was a small but statistically significant difference found between the usual care group and intervention group ($M = 10.1, SD = 5.5$ and $M = 11.8, SD = 6.1$, respectively), $t(186) = -1.95, p = .05$. There was no difference in drug treatment initiation regardless of group assignment. However, notably, 25 (13.3%) participants reported starting osteoporosis drug treatment at follow-up, of which 16 were in the intervention group compared to nine in the usual care group.
Table 16

*Calcium and Vitamin D Intake, Physical Activity, and Drug Treatment Initiation at Follow-up by Group*

<table>
<thead>
<tr>
<th></th>
<th>Usual Care</th>
<th>Intervention</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>n</em> = 93</td>
<td><em>n</em> = 95</td>
<td><em>t</em> (186)</td>
<td><em>p</em></td>
</tr>
<tr>
<td>Dietary calcium</td>
<td>779 ± 314</td>
<td>806 ± 307</td>
<td>-.59</td>
<td>.56</td>
</tr>
<tr>
<td>Calcium supplement</td>
<td>561 ± 473</td>
<td>785 ± 491</td>
<td>-3.19</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Total calcium</td>
<td>1,340 ± 544</td>
<td>1,590 ± 610</td>
<td>-2.97</td>
<td>.03</td>
</tr>
<tr>
<td>Dietary vitamin D</td>
<td>125 ± 132</td>
<td>119 ± 128</td>
<td>.30</td>
<td>.77</td>
</tr>
<tr>
<td>Vitamin D supplement</td>
<td>965 ± 783</td>
<td>1,210 ± 777</td>
<td>-2.15</td>
<td>.03</td>
</tr>
<tr>
<td>Total vitamin D</td>
<td>1,086 ± 780</td>
<td>1,329 ± 778</td>
<td>-2.13</td>
<td>.03</td>
</tr>
<tr>
<td>Physical activity</td>
<td>10.1 ± 5.5</td>
<td>11.8 ± 6.1</td>
<td>-1.95</td>
<td>.05</td>
</tr>
<tr>
<td>Drug treatment (yes)</td>
<td>9 (9.7)</td>
<td>16 (16.8)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note.* Calcium units are mg/day. Vitamin D units are IU/day. Physical activity based on mean score. Total calcium and vitamin D intake = diet and supplement. Chi-square test was used for comparison of means for drug treatment initiation.
Table 17 shows descriptive comparisons of participants who started or increased calcium intake (n = 119, 58.6%) and did not make a change (n = 69, 39.7%) and results of univariate logistic regression analyses of factors associated with change in calcium intake. Participants who changed their calcium intake were more likely to have been in the osteoporosis education intervention group and have diagnosis of osteoporosis compared to normal BMD. They were also more likely to start or increase calcium intake if they were over 65 years of age, had a total calcium intake < 1,200 mg/day, and discussed their DXA results with a HCP. Other factors significantly associated with change at p < .25 included dietary calcium intake at baseline (per 100 mg increase), use of calcium supplements, and family history of fracture.

Ten variables were found to have p < .25 and were thus included in the multivariate regression model (Table 18). Results from backward stepwise regression analysis showed receiving osteoporosis education intervention (OR = 2.49, p < .01, 95% CI [1.32, 4.69]) and baseline total calcium intake < 1,200 mg/day (OR = 2.98, p < .01, 95% CI [1.58, 5.60]) were statistically significant independent predictors of men and women’s decisions to start or increase calcium intake.
Table 17

Descriptive Statistics and Univariate Predictors of Change in Calcium Intake

<table>
<thead>
<tr>
<th>Factor</th>
<th>No change</th>
<th>Change</th>
<th>Unadjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$n = 69 (36.7%)$</td>
<td>$n = 119 (58.6%)$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$n$ or $M$ (SD)</td>
<td>$n$ or $M$ (SD)</td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>96% CI</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10</td>
<td>17</td>
<td>Referent</td>
</tr>
<tr>
<td>Female</td>
<td>59</td>
<td>102</td>
<td>1.02</td>
</tr>
<tr>
<td></td>
<td>[0.44, 2.37]</td>
<td></td>
<td>.97</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-64 years</td>
<td>55</td>
<td>84</td>
<td>Referent</td>
</tr>
<tr>
<td>65-80 years</td>
<td>14</td>
<td>35</td>
<td>1.64</td>
</tr>
<tr>
<td></td>
<td>[0.81, 3.32]</td>
<td></td>
<td>.17</td>
</tr>
<tr>
<td>Age (years) (per year increase)</td>
<td>59.6 (7.4)</td>
<td>60.1 (7.1)</td>
<td>1.01</td>
</tr>
<tr>
<td></td>
<td>[0.97, 1.05]</td>
<td></td>
<td>.64</td>
</tr>
<tr>
<td>Body mass (kg) (per unit increase)</td>
<td>74.7 (15.0)</td>
<td>74.1 (16.8)</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>[0.98, 1.02]</td>
<td></td>
<td>.83</td>
</tr>
<tr>
<td>Dietary calcium (mg)</td>
<td>829 (260)</td>
<td>753 (320)</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>[1.00, 1.00]</td>
<td></td>
<td>.10</td>
</tr>
<tr>
<td>Number of current medications</td>
<td>1.5 (1.4)</td>
<td>1.3 (1.2)</td>
<td>0.88</td>
</tr>
<tr>
<td></td>
<td>[0.70, 1.10]</td>
<td></td>
<td>.28</td>
</tr>
<tr>
<td>Use calcium supplements (yes)</td>
<td>50</td>
<td>62</td>
<td>0.41</td>
</tr>
<tr>
<td></td>
<td>[0.22, 0.78]</td>
<td></td>
<td>$&lt;.01$</td>
</tr>
<tr>
<td>Total calcium intake</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 1,200 mg/day</td>
<td>42</td>
<td>42</td>
<td>Referent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 1,200 mg/day</td>
<td>27</td>
<td>77</td>
<td>2.85</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>[1.55, 5.26]</td>
</tr>
</tbody>
</table>
Table 17 (continued)

<table>
<thead>
<tr>
<th>Factor</th>
<th>No change</th>
<th>Change</th>
<th>Unadjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$n = 69$ (36.7%)</td>
<td>$n = 119$ (58.6%)</td>
<td></td>
</tr>
<tr>
<td><em>n or M (SD)</em></td>
<td>%</td>
<td><em>n or M (SD)</em></td>
<td>%</td>
</tr>
<tr>
<td>DXA T-score level$^a$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>32</td>
<td>46.4</td>
<td>43</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>31</td>
<td>44.9</td>
<td>59</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>6</td>
<td>8.7</td>
<td>17</td>
</tr>
<tr>
<td>Randomized group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usual Care</td>
<td>43</td>
<td>62.3</td>
<td>50</td>
</tr>
<tr>
<td>Intervention</td>
<td>26</td>
<td>37.7</td>
<td>69</td>
</tr>
<tr>
<td>Routine medical care (more often than once yearly)</td>
<td>55</td>
<td>79.7</td>
<td>96</td>
</tr>
<tr>
<td>Fracture after 40 years of age (yes)</td>
<td>15</td>
<td>21.7</td>
<td>28</td>
</tr>
<tr>
<td>Family history of fracture (yes)</td>
<td>43</td>
<td>62.3</td>
<td>60</td>
</tr>
<tr>
<td>Discuss DXA results with HCP (yes)</td>
<td>33</td>
<td>47.8</td>
<td>70</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>3</td>
<td>4.3</td>
<td>10</td>
</tr>
<tr>
<td>Married/common-law</td>
<td>53</td>
<td>76.8</td>
<td>93</td>
</tr>
<tr>
<td>Divorced/widowed</td>
<td>13</td>
<td>18.8</td>
<td>16</td>
</tr>
</tbody>
</table>
Table 17 (continued)

<table>
<thead>
<tr>
<th>Factor</th>
<th>No change</th>
<th>Change</th>
<th>Unadjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>n or M (SD)</td>
<td>n or M (SD)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary/high-school</td>
<td>28</td>
<td>52</td>
<td>0.89</td>
</tr>
<tr>
<td>University/post-graduate</td>
<td>41</td>
<td>67</td>
<td>Referent</td>
</tr>
<tr>
<td>Income (&gt;$30,000)</td>
<td>55</td>
<td>89</td>
<td>0.67</td>
</tr>
<tr>
<td>Smoking status (current)</td>
<td>7</td>
<td>10</td>
<td>0.81</td>
</tr>
</tbody>
</table>

Note. OR = odds ratio. Total calcium intake = diet and supplement. DXA = dual energy x-ray absorptiometry. Bolded variables indicate those that had p < .25 associated with the regression coefficient in univariate analysis and were considered in the multivariate model.

a Lowest T-score for three sites measured by DXA (lumbar spine, right and left femoral neck). T-score level was based on WHO definitions for normal, osteopenia, and osteoporosis.
Table 18

*Multivariate Predictors of Change in Calcium Intake*

<table>
<thead>
<tr>
<th>Factor</th>
<th>Adjusted OR</th>
<th>OR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total calcium intake</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 1,200 mg/day</td>
<td>Referent</td>
<td>2.98</td>
<td>[1.58, 5.60]</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>&lt; 1,200 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomized group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usual Care</td>
<td>Referent</td>
<td>2.49</td>
<td>[1.32, 4.69]</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Intervention</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note.* OR = odds ratio. Total calcium intake = diet and supplement. OR adjusted for other variables in the multivariate logistic regression model.
Of the 188 participants completing follow-up, 131 (69.7%) started or increased vitamin D intake, while 57 (30.3%) did not make a change. Table 19 shows descriptive comparisons of participants and results of univariate logistic regression analyses of factors associated with change in vitamin D intake. Effect estimates for seven variables were found to have \( p < .25 \) and were considered in the multivariate regression model. Specifically, participants reporting change in vitamin D intake were more likely to have been in the osteoporosis education intervention group and have diagnosis of osteoporosis compared to normal BMD. They were also more likely to start or increase vitamin D intake if they were over 65 years of age, had a total vitamin D intake < 800 IU/day, and used fewer medications at baseline. Participants taking vitamin D supplements at baseline were nearly 70% less likely than those not taking supplements to start or increase vitamin D intake. Additionally, those reporting change in vitamin D intake were less likely to report a family history of fracture at baseline.

In multivariate logistic regression analysis (Table 20), factors independently associated with starting or increasing vitamin D intake were taking fewer medications at baseline \((OR = 0.65, p < .01, 95\% \text{ CI} [0.47, 0.90])\), not taking vitamin D supplements at baseline \((OR = 0.27, p = .01, 95\% \text{ CI} [0.10, 0.76])\), and no report of family history of fracture at baseline \((OR = 0.36, p = .02, 95\% \text{ CI} [0.15, 0.88])\).
### Table 19

**Descriptive Statistics and Univariate Predictors of Change in Vitamin D Intake**

<table>
<thead>
<tr>
<th>Factor</th>
<th>No change</th>
<th>Change</th>
<th>Unadjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( n = 57 ) (30.3%)</td>
<td>( n = 131 ) (69.7%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>( n ) or M (SD)</td>
<td>%</td>
<td>( n ) or M (SD)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
<td>14.0</td>
<td>19</td>
</tr>
<tr>
<td>Female</td>
<td>49</td>
<td>86.0</td>
<td>112</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-64 years</td>
<td>46</td>
<td>80.7</td>
<td>93</td>
</tr>
<tr>
<td>65-80 years</td>
<td>11</td>
<td>19.3</td>
<td>38</td>
</tr>
<tr>
<td>Age (years) (per year increase)</td>
<td>59.3 (7.0)</td>
<td>60.2 (7.3)</td>
<td>1.02 [0.98, 1.07]</td>
</tr>
<tr>
<td>Body mass (kg) (per unit increase)</td>
<td>75.7 (15.8)</td>
<td>73.8 (16.2)</td>
<td>1.00 [0.97, 1.01]</td>
</tr>
<tr>
<td>Dietary vitamin D (IU)</td>
<td>134 (121)</td>
<td>120 (126)</td>
<td>1.00 [1.00, 1.00]</td>
</tr>
<tr>
<td>Number of current medications</td>
<td>1.7 (1.4)</td>
<td>1.2 (1.8)</td>
<td>0.72 [0.57, 0.92]</td>
</tr>
<tr>
<td>Use vitamin D supplements (yes)</td>
<td>50</td>
<td>72.5</td>
<td>62</td>
</tr>
<tr>
<td>Total vitamin D intake</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( \geq 800 \text{ IU/day} )</td>
<td>24</td>
<td>64.9</td>
<td>36</td>
</tr>
<tr>
<td>(&lt; 800 \text{ IU/day} )</td>
<td>13</td>
<td>35.1</td>
<td>39</td>
</tr>
</tbody>
</table>
Table 19 (continued)

<table>
<thead>
<tr>
<th>Factor</th>
<th>No change</th>
<th>Change</th>
<th>Unadjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n or M (SD)</td>
<td>%</td>
<td>n or M (SD)</td>
</tr>
<tr>
<td><strong>DXA T-score level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>25</td>
<td>43.9</td>
<td>50</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>29</td>
<td>50.9</td>
<td>61</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>3</td>
<td>5.3</td>
<td>20</td>
</tr>
<tr>
<td><strong>Randomized group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usual Care</td>
<td>37</td>
<td>64.9</td>
<td>56</td>
</tr>
<tr>
<td>Intervention</td>
<td>20</td>
<td>35.1</td>
<td>75</td>
</tr>
<tr>
<td>Routine medical care (more often than once yearly)</td>
<td>47</td>
<td>82.5</td>
<td>104</td>
</tr>
<tr>
<td>Fracture after 40 years of age (yes)</td>
<td>16</td>
<td>28.1</td>
<td>27</td>
</tr>
<tr>
<td><strong>Family history of fracture</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(yes)</td>
<td>36</td>
<td>63.2</td>
<td>67</td>
</tr>
<tr>
<td>Discuss DXA results with HCP (yes)</td>
<td>29</td>
<td>50.9</td>
<td>74</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>3</td>
<td>5.3</td>
<td>10</td>
</tr>
<tr>
<td>Married/common-law</td>
<td>43</td>
<td>75.4</td>
<td>103</td>
</tr>
<tr>
<td>Divorced/widowed</td>
<td>11</td>
<td>19.3</td>
<td>18</td>
</tr>
<tr>
<td>Factor</td>
<td>No change</td>
<td>Change</td>
<td>Unadjusted OR</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>------------</td>
<td>-------------</td>
<td>---------------</td>
</tr>
<tr>
<td></td>
<td>n = 57 (30.3%)</td>
<td>n = 131 (69.7%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n or M (SD)</td>
<td>%</td>
<td>n or M (SD)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary/high-school</td>
<td>25</td>
<td>43.9</td>
<td>55</td>
</tr>
<tr>
<td>University/post-graduate</td>
<td>32</td>
<td>56.1</td>
<td>76</td>
</tr>
<tr>
<td>Income (&gt; $30,000)</td>
<td>53</td>
<td>93.0</td>
<td>121</td>
</tr>
<tr>
<td>Smoking status (current)</td>
<td>5</td>
<td>8.8</td>
<td>12</td>
</tr>
</tbody>
</table>

*Note. OR = odds ratio. Total vitamin D intake = diet and supplement. DXA = dual energy x-ray absorptiometry. Bolded variables indicate those that had $p < .25$ associated with the regression coefficient in univariate analysis and were considered in the multivariate model.

*a Lowest T-score for three sites measured by DXA (lumbar spine, right and left femoral neck). T-score level was based on WHO definitions for normal, osteopenia, and osteoporosis.
Table 20

*Multivariate Predictors of Change in Vitamin D Intake*

<table>
<thead>
<tr>
<th>Factor</th>
<th>Adjusted OR</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>95% CI</td>
<td>p</td>
</tr>
<tr>
<td>Family history of fracture (yes)</td>
<td>0.36</td>
<td>[0.15, 0.88]</td>
<td>0.02</td>
</tr>
<tr>
<td>Number of current medications</td>
<td>0.65</td>
<td>[0.47, 0.90]</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Use vitamin D supplements (yes)</td>
<td>0.27</td>
<td>[0.10, 0.76]</td>
<td>0.01</td>
</tr>
</tbody>
</table>

*Note.* OR = odds ratio. OR adjusted for other variables in the multivariate logistic regression model.
Table 21 shows descriptive comparisons of participants who started or increased physical activity \((n = 92, 48.9\%)\), and those who did not make a change \((n = 96, 51.1\%)\). Also presented are results of univariate logistic regression analyses of factors associated with change in physical activity. Effect estimates for 11 variables were found to have \(p < .25\) and were considered in the multivariate regression model. Specifically, participants who changed their physical activity were less likely to have osteopenia or osteoporosis compared to those with normal BMD. While osteoporosis education intervention was not associated with change in physical activity, it was included in the multivariate model because of its importance to the study design and hypothesis. Other factors found to be associated with change in physical activity included moderate to low physical activity levels and scores at baseline, female gender and younger age, not experiencing fracture after 40 years of age, not a current smoker, and taking fewer medications at baseline. Several sociodemographic variables were also associated with change in physical activity including higher education levels and being married/common law or divorced/widowed compared to single.

After adjusting for all variables significant at \(p < .25\), statistically significant independent predictors \((p \leq .05)\) of starting or increasing physical activity were lower physical activity scores at baseline \((OR \text{ per unit increase} = 0.84, p < .01, 95\% \text{ CI} [0.78, 0.91])\), taking fewer medications at baseline \((OR = 0.57, p < .01, 95\% \text{ CI} [0.43, 0.75])\), having higher BMD levels \((OR = 0.37, p < .01, 95\% \text{ CI} [0.18, 0.77])\), and not currently smoking \((OR = 0.21, p = .02, 95\% \text{ CI} [0.06, 0.74])\) (Table 22).
Table 21

Descriptive Statistics and Univariate Predictors of Change in Physical Activity

<table>
<thead>
<tr>
<th>Factor</th>
<th>No change</th>
<th>Change</th>
<th>Unadjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 96 (51.1%)</td>
<td>n = 92 (48.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n or M (SD)</td>
<td>%</td>
<td>n or M (SD)</td>
</tr>
<tr>
<td>Gender</td>
<td>Referent</td>
<td>Referent</td>
<td>Referent</td>
</tr>
<tr>
<td>Male</td>
<td>17 (17.7)</td>
<td>10 (10.9)</td>
<td>Referent</td>
</tr>
<tr>
<td>Female</td>
<td>79 (82.3)</td>
<td>82 (89.1)</td>
<td>Referent</td>
</tr>
<tr>
<td>Age</td>
<td>Referent</td>
<td>Referent</td>
<td>Referent</td>
</tr>
<tr>
<td>50-64 years</td>
<td>67 (69.8)</td>
<td>72 (78.3)</td>
<td>Referent</td>
</tr>
<tr>
<td>65-80 years</td>
<td>29 (30.2)</td>
<td>20 (21.7)</td>
<td>Referent</td>
</tr>
<tr>
<td>Age (years) (per year increase)</td>
<td>61.0 (7.9)</td>
<td>58.8 (6.2)</td>
<td>0.96</td>
</tr>
<tr>
<td>Body mass (kg) (per unit increase)</td>
<td>74.1 (16.0)</td>
<td>74.6 (16.3)</td>
<td>1.00</td>
</tr>
<tr>
<td>Number of current medications</td>
<td>1.6 (1.4)</td>
<td>1.1 (1.1)</td>
<td>0.70</td>
</tr>
<tr>
<td>Physical activity (score) (per unit increase)</td>
<td>12.5 (6.5)</td>
<td>9.2 (4.3)</td>
<td>0.89</td>
</tr>
<tr>
<td>Physical activity level</td>
<td>Referent</td>
<td>Referent</td>
<td>Referent</td>
</tr>
<tr>
<td>High</td>
<td>20 (20.8)</td>
<td>4 (4.3)</td>
<td>Referent</td>
</tr>
<tr>
<td>Moderate</td>
<td>38 (39.6)</td>
<td>32 (34.8)</td>
<td>Referent</td>
</tr>
<tr>
<td>Low</td>
<td>38 (38.6)</td>
<td>56 (60.9)</td>
<td>Referent</td>
</tr>
</tbody>
</table>
Table 21 (continued)

<table>
<thead>
<tr>
<th>Factor</th>
<th>No change $n = 96$ (51.1%)</th>
<th>Change $n = 92$ (48.9%)</th>
<th>Unadjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$n$ or $M$ (SD)</td>
<td>$%$</td>
<td>$n$ or $M$ (SD)</td>
</tr>
<tr>
<td><strong>DXA T-score level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>29</td>
<td>30.2</td>
<td>46</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>52</td>
<td>54.2</td>
<td>38</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>15</td>
<td>15.6</td>
<td>8</td>
</tr>
<tr>
<td><strong>Randomized group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usual Care</td>
<td>50</td>
<td>52.1</td>
<td>43</td>
</tr>
<tr>
<td>Intervention</td>
<td>46</td>
<td>47.9</td>
<td>49</td>
</tr>
<tr>
<td>Use calcium supplements (yes)</td>
<td>58</td>
<td>60.4</td>
<td>54</td>
</tr>
<tr>
<td>Use vitamin D supplements (yes)</td>
<td>60</td>
<td>62.5</td>
<td>61</td>
</tr>
<tr>
<td>Routine medical care (more often than once yearly)</td>
<td>80</td>
<td>83.3</td>
<td>71</td>
</tr>
<tr>
<td><strong>Fracture after 40 years of age</strong> (yes)</td>
<td>28</td>
<td>29.2</td>
<td>15</td>
</tr>
<tr>
<td>Family history of fracture (yes)</td>
<td>50</td>
<td>52.1</td>
<td>53</td>
</tr>
<tr>
<td>Discuss DXA results with HCP (yes)</td>
<td>54</td>
<td>56.3</td>
<td>49</td>
</tr>
</tbody>
</table>
Table 21 (continued)

<table>
<thead>
<tr>
<th>Factor</th>
<th>No change</th>
<th>Change</th>
<th>Unadjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 96 (51.1%)</td>
<td>n = 92 (48.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n or M (SD)</td>
<td>n or M (SD)</td>
<td>OR</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>11 (SD 65)</td>
<td>11.5%</td>
<td>2</td>
</tr>
<tr>
<td>Married/common-law</td>
<td>69 (SD 75)</td>
<td>71.9%</td>
<td>77</td>
</tr>
<tr>
<td>Divorced/widowed</td>
<td>16 (SD 70)</td>
<td>16.7%</td>
<td>13</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary/high-school</td>
<td>48 (SD 68)</td>
<td>50.0%</td>
<td>32</td>
</tr>
<tr>
<td>University/post-graduate</td>
<td>48 (SD 70)</td>
<td>50.0%</td>
<td>60</td>
</tr>
<tr>
<td>Income (&gt;30,000)</td>
<td>87 (SD 70)</td>
<td>90.6%</td>
<td>87</td>
</tr>
<tr>
<td>Smoking status (current)</td>
<td>12 (SD 70)</td>
<td>12.5%</td>
<td>5</td>
</tr>
</tbody>
</table>

Note. OR = odds ratio. DXA = dual energy x-ray absorptiometry. Bolded variables indicate those that had p < .25 associated with the regression coefficient in univariate analysis and were considered in the multivariate model.

*aLowest T-score for three sites measured by DXA (lumbar spine, right and left femoral neck). T-score level was based on WHO definitions for normal, osteopenia, and osteoporosis.
Table 22

*Multivariate Predictors of Change in Physical Activity*

<table>
<thead>
<tr>
<th>Factor</th>
<th>Adjusted OR</th>
<th>OR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA T-score levela</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>Referent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Osteopenia</strong></td>
<td>0.37</td>
<td>[0.18, 0.77]</td>
<td>&lt;.01</td>
<td></td>
</tr>
<tr>
<td><strong>Osteoporosis</strong></td>
<td>0.35</td>
<td>[0.11, 1.09]</td>
<td>.07</td>
<td></td>
</tr>
<tr>
<td>Physical activity (score) (per unit increase)</td>
<td>0.84</td>
<td>[0.78, 0.91]</td>
<td>&lt;.01</td>
<td></td>
</tr>
<tr>
<td>Fracture after 40 years of age (yes)</td>
<td>0.49</td>
<td>[0.22, 1.10]</td>
<td>.08</td>
<td></td>
</tr>
<tr>
<td><strong>Smoking status (current)</strong></td>
<td>0.21</td>
<td>[0.06, 0.74]</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Number of current medications</strong></td>
<td>0.57</td>
<td>[0.43, 0.75]</td>
<td>&lt;.01</td>
<td></td>
</tr>
</tbody>
</table>

*Note.* OR = odds ratio. DXA = dual energy x-ray absorptiometry. OR adjusted for other variables in the multivariate logistic regression model. Bolded variables have \( p \leq .05 \) and made up the final effects model.

* a Lowest T-score for three sites measured by DXA (lumbar spine, right and left femoral neck). T-score level was based on WHO definitions for normal, osteopenia, and osteoporosis.
Of the 103 participants who discussed their DXA results with their HCP, 25 initiated osteoporosis drug treatment (24.3%), and 78 did not initiate treatment (75.7%). Table 23 shows descriptive comparisons of participants initiated treatment and those who did not. The table also presents results of univariate logistic regression analyses of factors associated with initiated drug treatment. Effect estimates for five variables were found to have $p < .25$ and were considered in the multivariate regression model. Specifically, participants who initiated treatment were more likely to have lower T-score values, be over 65 years of age, or advancing age (per year increase), have a male HCP, and be less educated. While osteoporosis education intervention was not associated with treatment initiation, it was included in the multivariate model because of its importance to the study design and hypothesis. In multivariate logistic regression analysis, the only factor independently associated with treatment initiation was lower T-score values ($OR \text{ per unit increase} = 0.28, p < .01, 95\% \text{ CI} [0.13, 0.59]$).
Table 23

Descriptive Statistics and Univariate Predictors of Osteoporosis Drug Treatment Initiation in Participants who discussed their DXA Results with a HCP (n = 103)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Did not initiate treatment n = 78 (75.7%)</th>
<th>Initiated treatment n = 25 (24.3%)</th>
<th>Unadjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n or M (SD)</td>
<td>%</td>
<td>n or M (SD)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10</td>
<td>12.8</td>
<td>5</td>
</tr>
<tr>
<td>Female</td>
<td>68</td>
<td>87.2</td>
<td>20</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-64 years</td>
<td>54</td>
<td>69.2</td>
<td>13</td>
</tr>
<tr>
<td>65-80 years</td>
<td>24</td>
<td>30.8</td>
<td>12</td>
</tr>
<tr>
<td>Age (years) (per year increase)</td>
<td>60.6 (7.2)</td>
<td>63.3 (8.0)</td>
<td>1.05</td>
</tr>
<tr>
<td>Number of current medications</td>
<td>1.4 (1.3)</td>
<td>1.1 (1.3)</td>
<td>0.82</td>
</tr>
<tr>
<td>Length of relationship with HCP (per year increase)</td>
<td>7.7 (8.1)</td>
<td>9.7 (10.6)</td>
<td>1.03</td>
</tr>
<tr>
<td>Gender of HCP (female)</td>
<td>50</td>
<td>64.1</td>
<td>12</td>
</tr>
</tbody>
</table>
Table 23 (continued)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Did not initiate treatment</th>
<th>Initiated treatment</th>
<th>Unadjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>n</em> or <em>M</em> (SD)</td>
<td><em>n</em> or <em>M</em> (SD)</td>
<td><em>OR</em></td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>95% CI</td>
</tr>
<tr>
<td><strong>DXA T-score value</strong> (per unit increase)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>n</em> = 78 (75.7%)</td>
<td>1.47 (0.99)</td>
<td>2.54 (0.98)</td>
<td>0.28</td>
</tr>
<tr>
<td></td>
<td>[0.13, 0.59]</td>
<td></td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Randomized group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usual Care</td>
<td>34</td>
<td>9</td>
<td>Referent</td>
</tr>
<tr>
<td>Intervention</td>
<td>44</td>
<td>16</td>
<td>1.37</td>
</tr>
<tr>
<td>Routine medical care (more often than once yearly)</td>
<td>66</td>
<td>20</td>
<td>[0.54, 3.49]</td>
</tr>
<tr>
<td>Fracture after 40 years of age (yes)</td>
<td>18</td>
<td>7</td>
<td>1.3</td>
</tr>
<tr>
<td>Family history of fracture (yes)</td>
<td>45</td>
<td>13</td>
<td>0.79</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary/high-school</td>
<td>32</td>
<td>15</td>
<td>Referent</td>
</tr>
<tr>
<td>University/post-graduate</td>
<td>46</td>
<td>10</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>[0.19, 1.16]</td>
<td></td>
<td>.10</td>
</tr>
</tbody>
</table>

*Note. OR = odds ratio. DXA = dual energy x-ray absorptiometry. Bolded variables indicate those that had *p* < .25 associated with the regression coefficient in univariate analysis and were considered in the multivariate model.*

*a Lowest T-score value for three sites measured by DXA (lumbar spine, right and left femoral neck).*
Table 24

*Multivariate Predictors of Osteoporosis Drug Treatment Initiation*

<table>
<thead>
<tr>
<th>Factor</th>
<th>Adjusted OR</th>
<th>( OR )</th>
<th>95% CI</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA T-score value(^a) (per unit increase)</td>
<td>0.28</td>
<td>[0.13, 0.59]</td>
<td>&lt;.01</td>
<td></td>
</tr>
</tbody>
</table>

Note. \( OR = \) odds ratio. DXA = dual energy x-ray absorptiometry. \( OR \) adjusted for other variables in the multivariate logistic regression model.

\(^a\) Lowest T-score value for three sites measured by DXA (lumbar spine, right and left femoral neck).
6.6 Discussion

Results of this population-based experimental study demonstrate that theory-informed osteoporosis education combined with DXA screening increases calcium and vitamin D intake and physical activity compared to DXA screening alone in older men and women. Furthermore, in assessing factors associated with behaviour change, the intervention was found to be a strong independent predictor of change in calcium intake, but did not independently predict other health behaviours. DXA screening results, specifically receiving feedback of low BMD values, was an independent predictor of drug treatment initiation and those diagnosed with osteopenia were less likely to start or increase physical activity compared to those with normal BMD results. Overall, these findings highlight two important concepts. First, theory-informed osteoporosis education combined with DXA screening should be part of an integrated strategy for prevention and management of osteoporosis, particularly as it relates to calcium and vitamin D intake, and physical activity. Second, communication between HCPs and patients regarding DXA screening results is critical, especially regarding therapeutic decision-making.

In this study of previously unscreened men and women, it was an alarming finding that 49% were newly diagnosed with osteopenia and 11% were newly diagnosed with osteoporosis. Comparing prevalence in this study to the general Canadian population, Osteoporosis Canada estimates that one in four women and one in eight men over 50 have osteoporosis and approximately 46% of postmenopausal women and 40% of men over 50 have osteopenia. Given the mean age of study participants was 59.7 years, with majority (75%) ages 50 to 64 years, it was surprising that 60% were found to have low BMD. Since they were also unaware of their increased risk of osteoporosis and related fracture prior to the study and DXA screening, they may not have been taking
appropriate measures to prevent and manage the disease. This was evidenced at baseline by their low physical activity levels, and total calcium (1,137 mg/day) and vitamin D (742 IU/day) intakes below recommended levels of 1,200 mg/day and > 800 IU/day. It was also surprising that 60% of participants were found to have low BMD, yet only 54.8% reported having a discussion about their BMD results with their HCP six months after DXA screening. In a study by Rubin and Cummings, 95% of screened women reported discussing results with a HCP, and similar to this study, women were referred for screening by their HCP. These results suggest a critical need for follow-up consultations by HCPs as studies show women who discuss screening results with a HCP are more likely to make health behaviour changes for osteoporosis prevention and management (Fitt, et al., 2001; McLeod, et al., 2007).

6.6.1 Impact of Theory-based Osteoporosis Education

The theory-based osteoporosis education combined with DXA screening proved successful in significantly increasing calcium and vitamin D supplement intake, and total calcium and vitamin D intake compared to usual care (DXA screening only). This was an important finding as very few experimental studies have assessed the impact of participating in osteoporosis education and DXA screening with a comparison group receiving DXA screening only. The only experimental study using theory-informed education found no difference in calcium intake between groups (Sedlak, et al., 2005). However, as the authors noted, this may have been largely due to the study’s unequal sample sizes and other methodological shortcomings. In the present study, it is important to note that the usual care group also had statistically significant increases in calcium and vitamin D supplement use and thus total intake. These within group increases were anticipated for both groups as previous studies have shown significant increases in
calcium and vitamin D supplement use in older men and women after DXA screening (Doheny, et al., 2010; Rohr, et al., 2006; Rubin & Cummings, 1992). In the study by Sedlak et al. (2005), within group increases in calcium intake were significant for both the intervention and DXA screening group. Notably, no study has assessed the effect of a theory-based osteoporosis education intervention or DXA screening on change in vitamin D intake for comparison, though it was promising to see the significant impact of this theory-based intervention on this behaviour change.

While it was anticipated the education intervention combined with DXA screening would increase physical activity levels from baseline to follow-up, the small increase noted was not significant. However, compared to the usual care group, the intervention group had a small, but significant increase in physical activity. This may have been partially due to the decreased physical activity levels in the usual care group, but may have also been a result of the theory-informed education. While education may increase knowledge and help individuals make informed decisions, according to the RHBM, the likelihood of behavioural change at the individual level increases with increased self-efficacy, perceived seriousness and susceptibility, perceived benefits to carrying out a behaviour, and fewer perceived barriers (McLeod & Johnson, 2011). These health beliefs, as they relate to physical activity, were addressed in the osteoporosis education through fact sheets describing the benefits of exercise for healthy bones including the frequency, type, and duration of exercises to perform, video, adapting content to a local context, and providing incentive including a free day-pass to the fitness centre at the local university. While changes in physical activity were not significant from baseline to follow-up, this is presumably due to the fact that making a change in physical activity requires greater effort, skill and overall lifestyle adjustment than simply taking a
The use of skills-building involving home-based exercises or the use of pedometers may have been more likely to promote successful change in physical activity in the intervention group.

While it is evident theory-based osteoporosis education impacts health behaviour, the components of a program that best lead to increased awareness and behaviour change is still unclear. When designing health education interventions it is important to consider the target population, setting, and method of delivery, in addition to utilizing theory to guide development of the intervention. In this study, the intervention targeted individuals at risk of osteoporosis and related fracture who were over 50 years of age, and while all participants received the same general information about osteoporosis and its risk factors, the education packet was also tailored for older male participants.

The setting for the intervention involved one, one-on-one session lasting 25 to 30 minutes with the researcher in a comfortable research setting. This allowed for ease of interaction and effective communication between the participant and the researcher. Other experimental studies implementing theory-based osteoporosis education in community-based settings have carried out multiple group session approaches and found significant increases in calcium intake (Babatunde, et al., 2011). However, it has been suggested in a recent systematic review, that HCP-led interventions administered in one-on-one counseling are more advantageous than group sessions or passive interventions such as counseling via telephone or mailings (Lai, Chua, & Chan, 2010). A cross-sectional study of 175 individuals in waiting rooms of two hospitals in Ontario, identified features and factors influencing willingness to participate in health education intervention. The study found majority of respondents preferred to participate in one 30 to 60 minute education intervention per year, either in a hospital setting with a group or...
one-on-one with an educator or health care professional (Gucciardi, Cameron, Liao, Palmer, & Stewart, 2007). This was depicted in a prospective study of adults over 50 years presenting to emergency with mild to moderate trauma fracture. Results showed no difference in calcium intake or physical activity in those receiving a four-week, small group (12 to 20 persons), community based osteoporosis education course compared to a one-session course (Laslett, Lynch, Sullivan, & McNeil, 2011).

Traditionally, HCPs have been primarily responsible for knowledge translation and health promotion of osteoporosis in terms of education and recommendations to at-risk patients for prevention and management strategies outlined in practice guidelines (Papaioannou, et al., 2010). However, the optimal method for delivery of health promotion education is still debatable and a new paradigm is emerging where multifaceted interventions consisting of education, screening, and reminders, that involve patients, HCPs, and other stakeholders have improved management of osteoporosis compared to usual care (Ciaschini, et al., 2010; Kastner & Straus, 2008). The present study focused on at-risk individuals referred for first-time DXA screening by their HCP, a population where osteoporosis interventions may be best put to use to prevent or delay the onset of osteoporosis and related fracture. A multi-component education method including a take-home packet with print material, short video, and magnets were administered by the researcher. Also, the study involved buy-in from health care professionals including radiologists and a DXA technician, although HCPs were not targeted for the intervention. However, it was determined whether HCP discussed DXA screening results with their patients, and made recommendations for prevention and management strategies such as calcium and vitamin D intake or treatment prescription.
This was important to identify the role of HCPs recommendations in behaviour change, independent of the intervention or personal decision.

6.6.2 Change in Calcium Intake

An important focus of this study was to determine factors associated with change in behaviour six months after baseline, specifically the influence of theory-based education intervention and DXA screening results. Identifying primary factors associated with behaviour change is important as it provides insight to help guide health promotion efforts; however, few studies have evaluated these factors (Brennan, et al., 2004; Cranney, et al., 2009; McLeod, et al., 2007). At follow-up, 58.6% of men and women started or increased total calcium intake. After multivariate adjustment, men and women receiving the education intervention were 2.5 times as likely to make a change in their calcium intake compared to those in the usual care group. They were also three times as likely to start or increase calcium intake if they were consuming < 1,200 mg/day at baseline compared to those consuming ≥ 1,200 mg/day. Notably, after adjusting for other variables, point estimates for these factors increased from the unadjusted odds ratios, proving that the intervention and lower baseline calcium intake were strong independent predictors of change in calcium intake.

Osteoporosis diagnosis was associated with change in calcium intake in univariate analysis; however, it was not retained after multivariate adjustment. Despite this result, it is important to note that 14.3% of those with osteoporosis changed their calcium intake compared to 8.7% of those with osteoporosis who did not make a change. Those who did not make a change had higher calcium intake (≥ 1,200 mg/day) at baseline compared to those who made a change (60.9% vs 35.3%) and were also more likely to be using calcium supplements (72.5% vs 52.1%), therefore may not have felt the need to increase
intake. McLeod et al. (2007) found that osteopenia and osteoporosis diagnosis were independent predictors of calcium intake after adjusting for factors such as fracture history, calcium supplement use, and follow-up with a HCP. That study assessed previously unscreened, highly educated postmenopausal women, similar to the present study; however, it did not involve an education component and had a much higher proportion of participants newly diagnosed with osteopenia and osteoporosis (83.5%). As the present study suggests, calcium intake is enhanced when theory-based osteoporosis education is received in addition to DXA screening. Previous studies evaluating education combined with DXA on health behaviours are limited in their assessment of the confounding factors associated with a change; however, Marci, Viechnicki, and Greenspan (2000) found postmenopausal women were nearly 2.5 times as likely to start calcium supplements and 1.6 times as likely to increase dietary calcium intake if they had low BMD after adjusting for confounding variables such as age and fracture history. However, that was not an intervention study; therefore, the influence of DXA screening alone or combined with education on health behaviours was not compared.

Another important finding is that participants were nearly two times as likely to increase calcium intake if they had a follow-up consultation about their DXA results with their HCP. Similar results by McLeod et al. (2007) found postmenopausal women were 3.5 times as likely to increase calcium intake if they had discussed BMD results with a HCP. Overall, 54.8% of participants in the study discussed the results of their DXA screening with their HCP, of which 62.1% reported receiving a recommendation from their doctor to consume calcium (diet and/or supplement). This indicates the importance of HCP discussing osteoporosis prevention and management strategies with their patient and making recommendations.
6.6.3 Change in Vitamin D Intake

Regarding vitamin D intake, majority of men and women started or increased vitamin D intake; however, after adjustment, neither the intervention, nor DXA T-score level were associated with increased intake. Taking fewer medications and not taking vitamin D supplements at baseline were independent predictors of increasing vitamin D intake at follow-up. Of those who did not make a change, 72.5% were taking vitamin D supplements at baseline compared to 52.1% who made a change. Also, in univariate analysis, participants were two times as likely to make a change in vitamin D intake if they had total vitamin D intake < 800 IU/day. This suggests that baseline vitamin D intake and number of supplements and medications used were important predictors of change in intake.

In univariate analysis, participants with osteoporosis diagnosis were 3.3 times as likely, and those receiving the osteoporosis intervention were 2.5 times as likely to start or increase vitamin D intake; however, these variables were not retained after multivariate adjustment. Despite these results, it is likely both factors influenced vitamin D supplement intake as within group differences showed significant increases in vitamin D supplement use at follow-up, with those in the intervention group having a statistically significantly greater increase compared to those in the usual care group. No studies have evaluated factors associated with change in vitamin D intake, particularly the role of DXA screening and education for comparison. Rubin and Cummings (1992) found after screening, women reporting below normal BMD results were more likely to start vitamin D supplements compared to those reporting normal results; however, actual change in behaviour was unknown and it was unclear how vitamin D intake was measured. Vitamin D is critical for increasing and maintaining BMD and is a required nutrient for proper
absorption of calcium. Therefore, it is logical to assess factors associated with both calcium and vitamin D intake to provide a more accurate understanding of behaviour change to inform future health promotion efforts.

6.6.4 Change in Physical Activity

Changes in physical activity typically require greater effort, long-term commitment, and overall lifestyle adjustment compared to dietary changes. This study showed 48.9% of men and women started or increased physical activity compared to 51.1% who did not make a change. Univariate regression analysis showed men and women diagnosed with osteoporosis or osteopenia were less likely to start or increase physical activity compared to those with normal BMD. After adjusting for other variables associated with change in the univariate model, osteopenia was a strong, independent predictor of change in physical activity. These results were not surprising as studies have shown those with osteoporosis or osteopenia have increased fear of falling and are more likely to limit their activities to avoid falling (Marci, et al., 2000; Patel, et al., 2003).

While no studies have assessed the factors associated with change in physical activity after screening, Rubin and Cummings (1992) found women reporting below normal BMD were more likely to start or increase exercise compared to women reporting normal BMD results. However, women’s age ranged from 23 to 96 years; therefore, younger women may have been more physically able or willing to change their physical activity. Also, as previously noted, that study did not assess change in behaviour, measurement tools were not used to assess physical activity, and BMD levels were based on women’s self-report creating major room for bias. Only one study involving older men assessed change in physical activity using a validated measurement tool (the 39-item Yale Physical Activity Survey) and showed DXA results indicating osteopenia and
osteoporosis did not influence walking behaviour (Doheny, et al., 2010). The theory-based osteoporosis education intervention combined with DXA screening was not shown to be a predictor of change in physical activity. As previously suggested, a skills-based education program may be more beneficial in increasing self-efficacy and ultimately, likelihood of behaviour change for physical activity.

Several other factors were found to be independent predictors of physical activity. Specifically, men and women were more likely to make a change if they had lower physical activity scores, were non-smokers, and took fewer medications at baseline. This suggests that individuals are more willing to start or increase physical activity if they are in better state of health than those who are smoke and take multiple prescription and over-the-counter medications. Although not an independent predictor, univariate analysis showed men and women making a change in physical activity were 1.5 times as likely to be younger (50-64 years of age) compared to those ≥ 65 years of age. Initiating, increasing, or maintaining physical activity for older adults in particular, has been shown to require greater resources, social support, self-efficacy, and perceived safety (Cress, et al., 2006). Therefore, physical activity may be an arduous health behaviour to initiate, especially for the elderly, compared to taking a calcium and vitamin D supplement, or drug treatment.

6.6.5 Osteoporosis Drug Treatment Initiation

Osteoporosis drug treatments have demonstrated effectiveness in managing osteoporosis by reducing further bone loss and subsequent risk of fracture (Murad, et al., 2012). However, Canadian population-based studies show, even amongst high-risk men and women with fracture, less than 30% undergo screening, and less than 20% of women and only 10% of men are prescribed treatment (Giangregorio, et al., 2006; Papaioannou, 2006).
et al., 2004; Papaioannou, et al., 2008). Of the 103 participants (54.8%) in this study who discussed DXA results with their HCP, 31 (30.4%) were prescribed osteoporosis drug treatment and 25 (24.3%) initiated treatment. Of those who initiated treatment, 14 (56.0%) were diagnosed with osteoporosis, 10 (40%) were diagnosed with osteopenia, and one had normal BMD. While these results are promising compared to national, population-based data, according to DXA reports and the WHO definition, 10.3% \((n = 8)\) of participants diagnosed with osteoporosis and who discussed DXA screening results with their HCP did not initiate treatment. This was surprising, especially in Canada, where universal healthcare is available. Notably, of those who did not discuss DXA screening results with their HCP, one was diagnosed with osteoporosis, and 44.7% were newly diagnosed with osteopenia (results not shown) according to DXA reports.

Numerous barriers to the application of practice guideline by HCPs have been identified at the patient, provider, and healthcare system levels (Teng, Warriner, Curtis, & Saag, 2008). At the patient level, barriers include denial of osteoporosis and its risk factors, lack of awareness of osteoporosis treatment and prevention strategies and their efficacy, and lack of understanding of the seriousness of untreated osteoporosis (Teng, et al., 2008). At the physician level, some barriers include lack of recognition of fragility fractures as osteoporosis-defining events, resistance to change, lack of awareness of the morbidity, mortality and healthcare costs associated with osteoporosis, uncertainty of interpretation of DXA screening results, and reluctance to start a new treatment in elderly already taking many medications (Teng, et al., 2008). Last, at the system level, unwillingness of HCPs to assume responsibility for preventive care has been defined as a barrier. Taking this into consideration, it was worthwhile to investigate the role of DXA
screening alone or combined with theory-based education on drug treatment initiation in an at-risk group of men and women.

Advancing age, (65 yrs of age and older), having a male HCP, having lower level of education, and lower DXA T-score values were associated with treatment initiation. It is well-documented that advancing age is the strongest individual risk factor for osteoporosis, as are lower DXA T-score levels (Siris, et al., 2001). However, it was interesting to find that men and women with higher education levels were less likely to initiate drug treatment. Several studies, including a recent retrospective study conducted in Sweden of 645,429 men and women aged 75 to 89 years, showed higher education level was associated with use of osteoporosis drug treatment (Wastesson, Ringback, Parker, & Johnell, 2012). Similar results were found in another retrospective observational study, where higher level education and income was positively associated with treatment initiation after DXA screening (Brennan, et al., 2004). In the present study it is possible that men and women with lower education levels were less knowledgeable of osteoporosis risk factors and therefore, less likely to engage in preventive health behaviours in earlier years, ultimately increasing their risk of osteoporosis and need for treatment. Ultimately, universal health care in Canada enables greater access to treatment and it is important to point out that 40% of those who initiated treatment had higher levels of education.

After adjustment, lower DXA T-scores were found to be an independent predictor of treatment initiation, as expected. This finding is consistent with the literature showing that lower T-scores values or levels based on WHO criteria are associated with treatment initiation (Brennan, et al., 2004; Cranney, et al., 2009; Fitt, et al., 2001; Meadows, Mitchell, Bolge, Johnston, & Col, 2012). For example, a large historical cohort study
found low T-score values were associated with osteoporosis drug treatment initiation in Canadian women over 50 years of age (Cranney, et al., 2009). Also, it is estimated that for each standard deviation decrement in BMD T-score, there is an estimate 2-fold increase in fracture risk; therefore, treatment would be expected to increase with worsening T-score and increased fracture risk (Klotzbuecher, et al., 2000; P. D. Miller, et al., 2002).

The osteoporosis education combined with DXA screening did not increase likelihood of drug treatment initiation; however, this may have been due to the small number of participants initiating treatment, thus effect was lost. Nonetheless, of those initiating treatment, 64% received the intervention, compared to 36% in the usual care group. A recent systematic review on the effectiveness of education interventions to improve treatment of osteoporosis in primary care settings, determined multifaceted interventions aimed at at-risk individuals and their HCPs may be most effective in improving the management of osteoporosis, although improvements are often modest (Laliberte, Perreault, Jouini, Shea, & Lalonde, 2011). Ultimately, HCP-patient communication plays a critical role in the initiation of drug treatment after diagnostic screening and further understanding of the factors that influence decisions to screen for and treat osteoporosis may be useful in developing strategies to improve this level of care.

6.6.6 Strengths and Limitations

This population-based, experimental study was novel as it prospectively examined the influence of DXA screening combined with theory-informed osteoporosis education on health behaviour change in previously unscreened older men and women attending a primary care setting. Previous studies have been primarily community-based or
retrospective cohort studies involving postmenopausal women, focusing on DXA screening or education alone, with few having theoretical basis. In addition, no studies have focused on the multitude of preventive health behaviours necessary for osteoporosis prevention and management and important in understanding the full influence of screening and education intervention on change.

Other strengths of this study related to design and procedure included a randomized study design using an adequate randomization procedure and the use of validated questionnaires and measurement tools to assess calcium and vitamin D intake and physical activity at baseline and follow-up. Previous studies have been largely based on self-report (e.g., did you increase calcium supplement, yes or no?) (Rohr, et al., 2006; Rubin & Cummings, 1992; Sedlak, et al., 2005). Also, those in the usual care group still received an education information packet at 6-month follow-up, a decision that may have played a role in high retention rates, but more importantly ensured those in the usual care group were not disadvantaged with regard to the education provided from the study.

This study was also unique as it allowed for the ability to determine categorically which behaviour change effects were due to DXA screening alone (usual care) and which were due to DXA screening combined with education intervention (i.e., “enhanced care”). The intervention, targeted to at-risk men and women, and the “usual care” comparison group reflected individuals previously unscreened and unaware of their BMD results, yet referred for DXA screening and attending a primary care setting. Therefore, the study participants reflected a realistic, at-risk population who would typically be referred for DXA screening based on practice guidelines and/or diagnostic judgment of the HCP and less likely to be engaging in osteoporosis preventive or management behaviours. While the term “usual care” has been used throughout the study in reference
to participants who underwent DXA screening only, it is important to note that Canadian clinical practice guidelines outline an integrated approach to prevention and management of osteoporosis and related fractures – one that includes preventive behaviour modification including adequate calcium and vitamin D intake and physical activity. Unfortunately, majority of Canadians are unaware of osteoporosis risk factors and are not engaging in adequate health behaviours to prevent and manage the disease.

Perhaps one of the biggest strengths of this study lay in the successful application of a theory-based osteoporosis education intervention. Few studies have used a theory, specifically the RHBM, as a guiding framework for developing osteoporosis education programs. This intervention imparted not just knowledge, but facilitated behaviour change through health beliefs and cues to action (DXA screening). When developing the education curriculum, knowledge translation tools and resources by Osteoporosis Canada were used and built on by developing and incorporating materials that encompassed the various theory constructs (e.g., seriousness, barriers, and benefits), tailoring the education to men versus women, and adapting the content to a local context. In addition to using a theory-based approach, the education intervention was unique as it was multifaceted, including a packet of print material, viewing a short video, and easy-to-read magnets. It was also delivered in a one-on-one session. This allowed for open discussion and questions between the researcher and participant. Last, the study demonstrated a successful partnership between multiple stakeholders including radiologists and hospital staff, a DXA screening technician, and the Regina Chapter of Osteoporosis Canada. These groups played important roles at various stages throughout the research study.

Despite many strengths, there are also limitations that should be considered when interpreting the results of the study. Participants were primarily Caucasian,
postmenopausal women that limit generalization to the broader population of older adults. Also, participants were referred for screening by their HCP based on clinical risk factors and/or diagnostic judgement. Despite this, participants were representative of an at-risk population of men and women who would typically undergo DXA screening. However, those agreeing to participate in this bone health-oriented study were well-educated and likely more health-literate and may have been interested and willing to make health behaviour change. Therefore, it is not certain that results are generalizable to populations with lower levels of education.

Second, while a validated measurement tool was used to determine physical activity scores and level, participants may have overestimated their physical activity, a socially desirable behaviour. Also, the Modified Baecke Physical Activity Questionnaire considers habitual activity in the past year; however, the season during which the questionnaire was completed, may have influenced recollection and thus self-report of activities carried out. There is also a possible bias arising from self-reports of dietary and supplemental calcium and vitamin D intake, which may have led to overestimation/underestimation, despite the use of 3-day food records and medication/supplement tables at both baseline and follow-up. The study was not blinded; therefore, participants were aware they were taking part in an intervention study on bone health and behaviour change, increasing the potential for bias. However, baseline questionnaires were completed prior to participants’ knowledge of their group assignment. Last, a follow-up period of six months allowed for assessment of behaviour change, but did not allow for long term assessment of maintenance of behaviour at 12 months, or whether the intervention was effective in change maintaining BMD or reducing fracture.
6.7 Conclusion

Overall, these study results provided valuable insight to the osteoporosis care gap existing not only between best practice and actual delivery of care, but also from knowledge to practice as majority of men and women at risk of osteoporosis were not engaging in adequate prevention and management strategies at baseline, despite 60% being newly diagnosed with osteoporosis or osteopenia.

This study sought to identify the role of DXA screening combined with theory-informed osteoporosis education versus usual care (DXA screening alone) on health behaviour change in older men and women with no prior knowledge of their bone density status. Results showed that theory-informed osteoporosis education combined with DXA screening increases calcium and vitamin D intake and physical activity compared to DXA screening alone. Furthermore, the education intervention was found to be associated with calcium and vitamin D intake; however, independently the intervention predicted only change in calcium intake. DXA screening results, specifically, receiving feedback of low BMD values, was independently associated with drug treatment initiation and those with low BMD were less likely to start or increase physical activity compared to those with normal BMD.

Calcium and vitamin D intake, and physical activity are important modifiable factors for osteoporosis prevention and management; however, it is clear they require different approaches to target behaviour change. In addition, treatment initiation is based largely on DXA screening results and an individualized decision-making process between a patient and their HCP. Therefore, for an osteoporosis education intervention to have a positive impact, one-on-one theory-based education that is multifaceted and incorporates skill-building to increase self-efficacy should be performed. In addition, this multifaceted
intervention should target not only patients and HCPs, but community pharmacists, and other critical stakeholders interested in reducing the care gap to ensure continuity of care (Ciaschini, et al., 2010).
CHAPTER 7: CONCLUSIONS AND FUTURE DIRECTIONS

Osteoporosis is a multifactorial disease making its prevention and management complex. Reducing risk of osteoporosis and related fractures requires prevention and management strategies consisting primarily of adequate calcium and vitamin D intake, physical activity, early diagnostic screening by DXA, and appropriate drug treatment of high-risk individuals. However, there is a recognized care gap not only between best practice and actual care delivery, but also from knowledge to practice as men and women at risk of osteoporosis are not engaging in preventive health behaviours. This population-based study provided a unique opportunity to address the osteoporosis care gap in Saskatchewan by bringing together stakeholders with invested interest in reducing the care gap and improving continuity of care, including researchers, health care professionals (radiologists and a DXA technician), a community organization, (Osteoporosis Canada), and patients from the local hospital. The results of the three studies have provided valuable insight for practical solutions regarding improved detection of osteoporosis and useful strategies for osteoporosis education for prevention and management of the disease.

The first study evaluated the accuracy of QUS and OST in identifying older men and women with osteoporosis as defined by DXA and determined optimal risk cut-offs for these screening tests. Overall, it was determined that QUS was an effective pre-screening test for identifying older women with osteoporosis at the femoral neck. Specifically, a lower SI cut-off of < 65 was determined to warrant DXA screening. These findings demonstrate potential utility of QUS as a low-cost, portable, radiation-free, pre-screening test to assist HCPs in identifying which patients have high likelihood of osteoporosis and should undergo DXA screening. In Saskatchewan, access to diagnostic
screening is a challenge as a large portion of the population resides in rural areas and only three screening sites exist province-wide. Therefore, QUS would not only improve diagnostic screening efficiency, but may also be a valuable screening device in lieu of DXA, particularly in rural areas where access to DXA screening is limited. QUS may also play an important role in primary prevention of osteoporosis. Given the potential usefulness of QUS as a pre-screening test, it would be of interest to assess whether pre-screening results influence health behaviour change in men and women of all ages. Combined with osteoporosis education, this may prompt health behaviour change in early stages of bone loss rather than waiting for DXA screening and discussion of results with a HCP.

The second study determined the influence of DXA screening combined with theory-informed osteoporosis education versus usual care (DXA screening alone) on change in health behaviours in previously unscreened older men and women. Overall, it was determined that theory-informed osteoporosis education combined with DXA screening increases calcium and vitamin D intake and physical activity compared to DXA screening alone. Furthermore, the education intervention was independently associated with change in calcium intake and DXA screening results; specifically, receiving feedback of low BMD values was independently associated with drug treatment initiation. These findings provide a better understanding of the factors associated with health behaviour change among older men and women and will help inform health promotion programs targeted at improving calcium and vitamin D intake, physical activity, and treatment initiation and ultimately reduce fracture risk. Future studies will identify the health belief constructs predicting behaviour change in this group of men and women to better guide osteoporosis education content.
An integrated and comprehensive approach to osteoporosis and fracture prevention and management in Saskatchewan is necessary and must be aimed at DXA screening and health promotion education for behaviour change. When combined with timely, thorough follow-up, DXA screening is an important diagnostic tool assisting not only HCPs in making appropriate recommendations but also individuals’ decisions regarding health behaviours. However, to be effective and efficient, it requires compliance with practice guidelines and HCP recommendations after screening. In addition to screening, researchers must develop and evaluate comprehensive and innovative theory-based educational strategies that can be easily integrated with other primary care activities. For an osteoporosis education intervention to have a positive impact, future research should focus on developing, implementing, and evaluating one-on-one, theory-based education that is multifaceted and incorporates skill-building to increase self-efficacy. Furthermore, it may also be worthwhile if future research focused on multidisciplinary interventions targeting not only patients, and HCPs, but community pharmacists and other critical stakeholders interested in reducing the care gap to ensure continuity of care (Ciaschini, et al., 2010). Currently, a paradigm shift in focus from treating low BMD to preventing and treating osteoporosis related fractures is occurring. Therefore, future research is also needed to understand health beliefs and health behaviours associated with those at risk of fracture or who have suffered fragility fracture (e.g., determining factors associated with treatment of men and women with fragility fracture).

Last, the results of these two studies clearly show that men with osteoporosis are identified and treated less often than women. There is an overall need for studies that evaluate osteoporosis detection, prevention, and management in men, including the
diagnostic accuracy of QUS in older men, identifying the rate of diagnostic screening in men, and examining the knowledge and factors associated with health behaviour change in men.
REFERENCES


Health Quality Council. 2003. *Bone mineral density testing services in Saskatchewan.* Saskatchewan, Canada


Kastner, M., & Straus, S. E. (2008). Clinical decision support tools for osteoporosis


APPENDIX A

UNIVERSITY OF
REGINA

OFFICE OF RESEARCH SERVICES

MEMORANDUM

DATE: March 25, 2010

TO: Katherine M. McLeod
Kinesiology and Health Studies

FROM: Dr. Bruce Plouffe
Chair, Research Ethics Board

Re: A Study of Osteoporosis Screening, Prevention, and Management
(File # 7050910)

Please be advised that the University of Regina Research Ethics Board has reviewed your proposal and found it to be:

1. APPROVED AS SUBMITTED. Only applicants with this designation have ethical approval to proceed with their research as described in their applications. For research lasting more than one year (Section 1F), **ETHICAL APPROVAL MUST BE RENEWED BY SUBMITTING A BRIEF STATUS REPORT EVERY TWELVE MONTHS.** Approval will be revoked unless a satisfactory status report is received. Any substantive changes in methodology or instrumentation must also be approved prior to their implementation.

2. ACCEPTABLE SUBJECT TO MINOR CHANGES AND PRECAUTIONS (SEE ATTACHED). Changes must be submitted to the REB and approved prior to beginning research. Please submit a supplementary memo addressing the concerns to the Chair of the REB. **Do not submit a new application.** Once changes are deemed acceptable, ethical approval will be granted.

3. ACCEPTABLE SUBJECT TO CHANGES AND PRECAUTIONS (SEE ATTACHED). Changes must be submitted to the REB and approved prior to beginning research. Please submit a supplementary memo addressing the concerns to the Chair of the REB. **Do not submit a new application.** Once changes are deemed acceptable, ethical approval will be granted.

4. UNACCEPTABLE AS SUBMITTED. The proposal requires substantial additions or redesign. Please contact the Chair of the REB for advice on how the project proposal might be revised.

Dr. Bruce Plouffe

cc: Dr. Shanthi Johnson – Faculty of Kinesiology and Health Studies

**supplementary memo should be forwarded to the Chair of the Research Ethics Board at the Office of Research Services (Research and Innovation Centre, Room 109) or by e-mail to research.ethics@uregina.ca**
DATE:             April 9, 2012

TO:               Dr. Shanthi Johnson  
                  Katherine McLeod  
                  Kinesiology and Health Studies

FROM:             Mei gen Schmidt  
                  Research Ethics Board

RE:               Annual Research Status Report

Thank you for submitting the required Annual Research Status Report on your project entitled, “A Study of Osteoporosis Screening, Prevention, and Management.” File 7050910.

This memo confirms ethical clearance for an additional 12 months, beginning March 25, 2012.

Sincerely,

Melgen Schmidt  
Senior Research Officer  
Office of Research Services
Certificate of Approval
Research Ethics Board

PRINCIPAL INVESTIGATOR: Dr. Shanthi Johnson
Faculty of Kinesiology & Health Studies
University of Regina
3737 Wascana Parkway
Regina SK

APPROVAL DATE: July 16, 2010

RQHR PROJECT #: REB-10-34

TITLE: A Study of Osteoporosis Screening, Prevention and Management

APPROVED: Amendment
-Recruitment Card – Version 1, July 15, 2010

CERTIFICATION

The protocol and consent form for the above named project have been reviewed by the Regina Qu’Appelle Health Region Research Ethics Board and the experimental procedures were found to be acceptable on ethical grounds for research involving human subjects.

The Regina Qu’Appelle Health Region Research Ethics Board meets the standards outlined by Canada’s Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans.

The Regina Qu’Appelle Health Region Research Ethics Board has met the criteria for purposes of Section 29 of the Health Information Protection Act.

Please note that all future correspondence regarding this project must include the RQHR project number.

Best wishes in your continuing research endeavours.

[Signature]

Dr. Elan Paluck, Chair
Regina Qu’Appelle Health Region
Research Ethics Board

cc: Ms. C. Klassen, Knowledge Management & Strategic Development, WRC

This Certificate of Approval is valid provided there is no change in the experimental procedures. Any significant changes to the protocol must be reported to the Chair for the Board’s consideration, in advance of implementation of such changes. You are required to provide a status report on an annual basis.
Certificate of Reapproval
Research Ethics Board

PRINCIPAL INVESTIGATOR  Dr. Shanthi Johnson
Faculty of Kinesiology & Health Studies
University of Regina
3737 Wascana Parkway
Regina SK

Co-Investigators:

REAPPROVAL DATE  May 31, 2011
RQHR PROJECT #  REB-10-34

TITLE  A Study of Osteoporosis Screening, Prevention and Management

Protocol  Sponsor:

CERTIFICATION

The above referenced protocol has been the subject of expedited review by the Chair of the Regina Qu’Appelle Health Region Research Ethics Board and has been granted reapproval.

Any significant changes to the protocol must be reported to the Chair for the Board’s consideration, in advance of implementation of such changes. You will be asked for a status report and must apply for reapproval within one year of the above reapproval date.

If you have any questions, please contact me at your convenience. Best wishes in your continuing investigation.

The Regina Qu’Appelle Health Region Research Ethics Board meets the standards outlined by Canada’s Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans.

[Signature]
Dr. Elan’Palaec, Chair
Regina Qu’Appelle Health Region
Research Ethics Board

/lh

280
Participants Wanted for a Research Study on **BONE HEALTH**

You may participate in this study if you are...

→ Male or female and recently had your first DXA (bone density) screening
→ 50 years of age and older

If you are interested in participating and would like additional information, please ask your DXA technician for a letter of invitation to the study or contact Katherine McLeod by phone: (306) 337-3329 or email: Katherine.McLeod@uregina.ca

Principal Investigators:
Katherine McLeod, PhD Candidate, MSc
Dr. Shanthi Johnson, RD
Faculty of Kinesiology and Health Studies
University of Regina

*All participants in this study will be compensated*

Project approved by University of Regina and the Regina Qu’Appelle Health Region Research Ethics Board
Participants wanted for a Research Study on HEALTHY BONES

Are you interested in this research study?

☐ Yes  ☐ No

If YES, please provide your name and phone number. We will contact you with further details about the study. Study information can also be found in the letter of invitation.

Name ____________________________

Phone ____________________________

Date of BMD Scan __________________

Principal Investigators:
Katherine McLeod, PhD candidate, MSc & Dr. Shanthi Johnson, RD
Faculty of Kinesiology & Health Studies, University of Regina
Approved by University of Regina and Regina Qu’Appelle Health Region Research Ethics Board
APPENDIX C

LETTER OF INVITATION

A Research Study on Bone Health

The purpose of this study is to compare the effectiveness of three osteoporosis screening techniques and determine the influence of bone density screening alone, and combined with osteoporosis education on health behaviour change in men and women. This study is being conducted by, Katherine McLeod, a PhD candidate under the supervision of Dr. Shanthi Johnson, in the Faculty of Kinesiology and Health Studies at the University of Regina. Approximately 300 men and women 50 years of age and older who have recently undergone DXA screening for the first time will be recruited for this study from the Radiology Department within the Regina General Hospital.

About the Research Study

Osteoporosis is a silent disease that causes bones to become fragile and increases the risk of fracture, particularly of the hip, spine, and wrist. In Canada, about 1.4 million suffer from the disease of which one in four are women and one in eight are men over 50 years of age. Dual energy x-ray absorptiometry (DXA) is the gold standard screening method for bone mineral density, however new screening techniques including heel ultrasound may be useful to aid in the screening process.

Research shows that individuals who have osteoporosis and have suffered a fracture do not engage in health behaviours to reduce their risk. It is important that older adults make appropriate decisions about their health to better maintain healthy bones.

This study will proceed in three stages and involve two brief visits to the University of Regina:

1.) Participants who have recently undergone DXA screening will be mailed a parking permit and directions to the university/lab, as well as a series of brief questionnaires to complete about their health history, nutrition intake, and physical activity.

2.) Participants will visit the University of Regina and have a heel ultrasound as well as their height, weight, and body composition measured. Participants in this study will be randomly placed in either an experimental or control group. Both experimental and control groups will complete all study procedures; however those in the experimental group will also receive osteoporosis education. The visit will last no more than 45 min.

3.) Approximately six months later, participants will complete a series of brief questionnaires including a follow-up questionnaire and a heel ultrasound. (Note: If you travel south in the winter months, we will make arrangements upon your return). This visit will last 20 min.
Risks and Benefits
The information from this study will provide older adults, health care providers, and health care institutions in Saskatchewan and throughout Canada, practical solutions for osteoporosis prevention, education, detection, and treatment. There are no known risks associated with this study. All participants in the study will be compensated.

Confidentiality
Any information that is obtained during this study will be kept confidential to the full extent permitted by law. Participants will be given a unique identification number and any information provided will be marked with this ID number. Your identity will not be associated with any published results. Materials will be locked on password protected computer files, with paper versions of these files kept in a locked filing cabinet. Only Katherine McLeod (primary investigator) and Dr. Shanthi Johnson (primary investigator/supervisor) will have access to these materials.

Freedom to Withdrawal
If you feel, at any time, that you would like to withdraw from the research study, you may do so freely and without consequence. You also have the option to remove your data from the research study at any time.

If you have any questions about the study, Katherine McLeod can be contacted by telephone at: (306) 337-3329 or by email at: Katherine.McLeod@uregina.ca. Dr. Shanthi Johnson, can also be contacted by telephone at (306) 337-3180 or through email at: Shanthi.Johnson@uregina.ca.

This research has been approved by the University of Regina Research Ethics Board (telephone: (306) 585-4775 email: research.ethics@uregina.ca) and the Regina Qu’Appelle Health Region Research Ethics Board (telephone: (306) 766-5451).

Thank you in advance for your participation,

Katherine McLeod, PhD candidate, MSc

Shanthi Johnson, PhD, RD
APPENDIX D

Bone Health Research Study

ELIGIBILITY SCREENING FORM

Today’s Date: __________/________/________

Month Day Year

1. Name: __________________________________________
   First Last

2. Your gender: _____ Male
   _____ Female

3. What is your date of birth? __________/________/________
   month day year

   a. What is your age?: ___________ years

4. Did you recently undergo bone density screening test (DXA) for the first time?  
   Yes  No

   a. If “NO”, how many times have you received a bone density screening test? __________

   b. If “YES”, when was your screening appointment? __________/________/________
      month day year

   i. Have you discussed your bone density screening results with your doctor?  Yes  No

5. Have you ever been diagnosed with osteoporosis by your doctor?  Yes  No

6. Have you ever received treatment for osteoporosis?  Yes  No

   a. If “YES”, what treatment did you receive? (e.g. hormone therapy, fosamax, etc.)

   b. Are you currently receiving treatment for osteoporosis?  Yes  No

   c. If “NO”, when was the last time you took this treatment? __________/________
      month year

7. In the past year have you been diagnosed or hospitalized with any of the following medical 
   conditions:

   No  Yes
   Cancer  If “YES”, specify type: _____________________________

   No  Yes
   Heart attack

   No  Yes
   Stroke

   No  Yes
   Kidney/Renal Failure

   No  Yes
   Liver disease (chronic active hepatitis, cirrhosis, yellow jaundice?)
8. Have you ever been diagnosed with dementia? Yes No

9. Are there any reasons such as serious emotional problems, mental illness, or too much stress that would make it hard for you to be in a research study? Yes No

10. Are you currently receiving any palliative care for a terminal condition? Yes No
   a. If “YES”, specify the condition: ________________________________

11. Are you currently living in long term care or assisted living facility? Yes No

12. Will you be able to come to our lab for approximately 1 hour? Yes No
   a. Will you need any help or assistance to come to the lab? Yes No
      i. If “YES”, what kind of help (e.g., transportation): ________________________________

Personal Information

Home Address

Address: ____________________________________________________________

City, Province, Postal Code: __________________________________________

Home Phone: (306) ________________________________

(If this is not your year-round mailing address provide dates: ___/___/___ to ___/___/___)

Second Address

Address: ____________________________________________________________

City, Province, Postal Code: __________________________________________

Home Phone: ________________________________

Work Phone: (___) __________ May we call you at work? Yes No

Other Phone: (___) __________ Whose phone? ______________________

Best time to contact you: ____________________________________________

E-mail address: ____________________________________________________
APPENDIX E

University of Regina

Regina Qu’Appelle HEALTH REGION

SUBJECT INFORMATION AND CONSENT FORM

Bone Health Research Study

It is a principle of medical ethics that participants of a research protocol be informed of the purpose, procedure, and benefits of the project, the potential risks of participation, and the right to ask questions at any time during the research procedure. Your signature at the end of this consent form will indicate that the primary investigator has answered all your questions and that you voluntarily consent to participate in this study. Please take time to read the following information carefully.

Primary Investigators:
Katherine M. McLeod, PhD Candidate, MSc
Faculty of Kinesiology and Health Studies
University of Regina
Phone: (306) 337-3329
Email: Katherine.McLeod@uregina.ca

Dr. Shanthi Johnson, Professor (Supervisor)
Faculty of Kinesiology and Health Studies
University of Regina
Phone: (306) 337-3180
E-mail: shanthi.johnson@uregina.ca

Emergency contact: (306) 581-5423

INTRODUCTION
You are being asked to participate in a research study that will collect information on osteoporosis and health behaviours in men and women 50 years of age and older.

YOUR PARTICIPATION IS VOLUNTARY
Your participation in this study is completely voluntary, so it is up to you to decide whether or not to take part in this study. This consent form will tell you about the study, why the research is being done, what will happen to you during the study, and possible benefits and risks.

If you wish to participate, you will be asked to sign this form. You are free to discontinue participation in this study at any time without question or penalty. Please take time to read the following information and to discuss with your family, friends, and doctor before you decide.

WHO IS CONDUCTING THE STUDY?
This study is funded by the Canadian Institute of Health Research and Saskatchewan Health Research Foundation and is being conducted by Katherine McLeod, a PhD candidate, and her supervisor Dr. Shanthi Johnson, a professor, both in the Faculty of Kinesiology and Health Studies at the University of Regina.

BACKGROUND
Osteoporosis is a silent disease that causes bones to become fragile. This increases the risk of fracture, particularly of the hip, spine, and wrist. It can often lead to disability or even death. In Canada, about 1.4 million suffer from the disease of which one in four are women and one in eight are men over 50 years of age. In Saskatchewan, 38,000 women and 18,000 men have osteoporosis and these numbers continue to rise as the population ages. In Canada, each year osteoporosis and related fractures cost the healthcare system $1.9 billion making it a major public health concern.
Dual energy x-ray absorptiometry (DXA) is the gold standard method for osteoporosis screening. However, across Canada, and particularly in Saskatchewan, there is limited access to this screening technology. New screening techniques including heel ultrasound may be useful to aid in the screening process.

Research shows that those who have osteoporosis and have suffered a fracture are not engaging in health behaviours to reduce their risk. It is important that older adults are aware of osteoporosis and its risks so they can make decisions about their health to better prevent and manage the disease. Research examining the influence osteoporosis education and screening on health behaviours is lacking.

PURPOSE OF THE STUDY
Your participation in this study will help investigators understand the usefulness of different osteoporosis screening techniques and the care gap with regard to prevention and management of the disease. Specifically, we will compare the effectiveness of three screening techniques, and determine the influence of DXA screening alone, and combined with osteoporosis education on health behaviours. You have been asked to join because you have recently had your first bone mineral density screening by a DXA.

WHO CAN PARTICIPATE IN THE STUDY?
Men and women 50 years of age and older recruited through the radiology department of the Regina General Hospital, who have undergone DXA screening for the first time in the past month, and are willing to sign a letter of informed consent.

WHO SHOULD NOT PARTICIPATE IN THE STUDY?
Older adults who: have previous diagnosis and or treatment for osteoporosis, have advanced cognitive impairment of any kind, have unstable medical conditions, have palliative conditions and or terminal conditions, are unable to read, write, or understand the English language.

STUDY PROCEDURES
This study is taking place at the University of Regina and will enroll 300 volunteer subjects. The study will last for 6 months and require only two visits (once at the beginning and once at the end of the study) to the Centre for Exercise and Nutrition in Falls and Aging Research (CENfAR) at the University of Regina. At the end of the study; if you are interested, your continued participation may be requested for a follow-up 6 months after the end of the study.

Overview of the Study:
There will be two groups in this study, an experimental group and a control group. Upon entering the study, you will be randomly placed into one of the two groups. Randomization will be decided by a computer so there is equal chance of being in any of the groups. Both experimental and control groups will complete all study procedures; however those in the experimental group will also receive osteoporosis education.

Specific Study Procedures:
If you agree to join this study, the procedures and visits you can expect will include the following:

Initial Screening
When contacting the primary researcher you will be asked a series of questions to ensure that you meet the inclusion criteria. If you are eligible to participate, a baseline visit to the Centre for Exercise and Nutrition in Falls and Aging Research (CENfAR) at the University of Regina will be scheduled. Prior to your visit, you will receive a package containing this letter of informed consent for your initial review to be signed on the day of your baseline visit. Also included in the package will be a series of brief questionnaires for you to complete prior to your baseline visit. These include: a health history questionnaire, a three day food
record, and a physical activity questionnaire. Instructions for completing the questionnaires will also be provided.

**Baseline Study Visit**
At your baseline visit to the Centre for Exercise and Nutrition in Falls and Aging Research (CENfAR) at the University of Regina, you will return your consent form and the questionnaires in the package that you were asked to complete prior to your visit. The study investigator will explain the informed consent to be signed and review your questionnaires for completion. By signing the consent form, you will agree to allow your DXA screening results to be obtained from your health care provider. You will then be given three brief questionnaires to complete about your health beliefs. You will also undergo measures for height, weight, and body composition, and a heel ultrasound. At this point, if you were randomized to the experimental group, you will also receive osteoporosis education consisting of a video and printed material developed by Osteoporosis Canada.

**Expected Follow-up**
Six months after your visit, you will be asked to complete a three day food record, physical activity and health beliefs questionnaire, a follow-up questionnaire, and a short visit to the Centre for Exercise and Nutrition in Falls and Aging Research (CENfAR) for a heel ultrasound. Time required for all Labvisits is estimated at 45 minutes.

**WHAT ARE MY RESPONSIBILITIES?**
You will be required to complete a series of questionnaires prior to your baseline visit, and at six month follow-up.

**RISKS AND BENEFITS OF PARTICIPATING IN THIS STUDY**
The information from this study will provide older adults, health care providers, and health care institutions in Saskatchewan and throughout Canada, practical solutions for osteoporosis prevention, education, detection, and treatment; however there may or may not be direct benefits to you from taking part in this study. A one-page summary of the general findings from this study will be provided to you upon completion of this study. There are no known risks associated with this study.

**WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?**
If, during the course of this study, new information becomes available that may be related to your willingness to continue to participate, this information will be provided to you by the study investigators.

**WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?**
Your participation in this research is entirely voluntary. If you choose to enter the study and then decide to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected. All data collected about you during your enrolment in the study will be removed should you choose to withdraw.

The study investigators may decide to discontinue the study at any time, or withdraw you from the study at any time, if they feel that it is in your best interests.

**WHAT HAPPENS IF SOMETHING GOES WRONG?**
You do not waive any of your legal rights to compensation by signing this consent form. There will be no costs to you for participating in this study.
CAN I BE ASKED TO LEAVE THE STUDY?
If you are not complying with the requirements of the study, the researchers may withdraw you from the study and will arrange for your care to continue.

AFTER THE STUDY IS FINISHED
Once results have been tabulated, a one page summary will be sent to each subject through mail or email.

WHAT WILL THE STUDY COST ME?
For your participation, you will receive a one-day pass to the Fitness and Lifestyle Centre at the University of Regina and a parking pass to use at your study visits. Your name will also be entered into one of three $100 draws and one of ten gift certificate draws.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?
Your privacy will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the investigator or his/her qualified designate. Health Canada, and the Regina Qu’Appelle Health Region Research Ethics Board for the purpose of monitoring the research. Rarely, your study documents may be obtained by courts of law. This type of access to your personal health information may include copying and taking copies of your personal health information away.

Your identity will be coded and any information provided will be marked with this identification number. Your identity will not be associated with any published results. Your study documents and identity will be locked on password protected computer files, with paper versions of these files kept in a locked filing cabinet located in the primary investigator’s office. Only Katherine McLeod and Dr. Shanthi Johnson will have access to these documents. Upon completion of the study, the results will be used in a Ph.D. dissertation, presented at conferences, and submitted for journal publication.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?
If you have any questions or desire further information about this study before or during participation, you can contact Katherine McLeod at 306-337-3529, or Shanthi Johnson at 306-337-3180.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT DURING THE STUDY?
This research has been approved by the University of Regina Research Ethics Board and the Regina Qu’Appelle Health Region Research Ethics Board. If you have any concerns about your rights or treatment as a research subject and/or your experiences while participating in this study, contact either the Chair of the Research Ethics Board at the University of Regina. Phone: (306) 585-4775; Email: research.ethics@uregina.ca or Dr. Elan Paluck, Chair of the Regina Qu’Appelle Health Region Research Ethics Board, at (306) 766-5451
SUBJECT CONSENT TO PARTICIPATE

- I have read and understood the subject information and consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.
- I have read this form and I freely consent to participate in this study.
- I have been told that I will receive a dated and signed copy of this form.
- I am aware that Katherine McLeod and Dr. Shanthi Johnson (primary researchers) will have access to my DXA screening results.

SIGNATURES

________________________________________________________________________
Signature of Subject

Name of Subject (print) ___________________________ Date ______________

________________________________________________________________________
Signature of Witness

Name of Witness (print) ___________________________ Date ______________

________________________________________________________________________
Signature of Primary Researcher

Name of Primary Researcher (print) ___________________________ Date ______________
APPENDIX F

June 14th, 2011

Dear **************,

Thank you for your interest in our “Bone Health” research study. We are looking forward to seeing you for your study visit on ________________ at _____________.

Directions to the parking location and our lab at the University of Regina:

- Park in Lot 4 at the University of Regina
- Enter the side doors of the Centre for Kinesiology, Health and Sport
- Follow the hallway straight down to the main staircase on the right which leads to the Fitness and Lifestyle Centre
- Go up the first flight of stairs and turn right following signs to the Centre for Exercise and Nutrition in Falls and Aging Research (CENfAR) (NOTE: there is also an elevator to the left of the stairs – choose floor 2 (not 2A).
- Follow overhead CENfAR signs down the hallway to end at main doors (room 210)

Please bring with you:

✓ Women: A bathing suit or spandex shorts/leggings and sports bra (or shorts and tank top if you do not have a bathing suit); Men: gym shorts or spandex shorts. This attire is necessary for accurate body composition testing in the Bod pod. The Bod pod measurement does not involve water. You may wear these garments under your clothes or change into them prior to the test.

The entire visit will take no more than 45 minutes. If you cannot keep your appointment and need to reschedule or if you have any questions with the paperwork, please call Katherine McLeod at 337-3329 (emergency contact: 581-5423). Thank you again for your interest and support of this important study. We look forward to seeing you soon.

Sincerely,

Katherine McLeod, PhD candidate, Primary Investigator
Faculty of Kinesiology and Health Studies
University of Regina
APPENDIX G

ID Number: ____________________

Health History Questionnaire

Below you will find a number of questions regarding your health. Please answer all questions to the best of your ability. If you are not sure of an answer, give the best answer you can. If you have any questions please feel free to call the primary investigator.

Part I. Personal Information

Today’s Date: ______/_____/_____
   Month  Day  Year

1. Your gender:  ____ Male
    ____ Female

2. What is your ethnicity?
   □ Caucasian
   □ Black or African
   □ Asian
   □ Hispanic
   □ First Nations or Inuit
   □ Metis
   □ Other: __________________________

3. What is your age? ________ years

4. What is your marital status?
   □ Single
   □ Married
   □ Common law / Living with partner
   □ Separated / Divorced
   □ Widowed

5. What is the highest level of formal education you have completed?
   □ Elementary / Grade school
   □ High school
   □ College / University
   □ Post-graduate: ______________________

6. What is your current employment status?
   □ Employed / Self-employed
   □ Home-maker
   □ Retired / Semi-retired
   □ Social Assistance or Disability
   □ Unemployed
7. What is your current occupation (or last, if retired)? ________________________

8. Including yourself, how many people live within your household? _____________

9. What is your current annual combined household income (Canadian dollars)?
   □ Less than $30,000
   □ $30,000 to $39,999
   □ $40,000 to $49,999
   □ $50,000 to $59,000
   □ Greater than $60,000
   □ Choose not to answer

Part II. Osteoporosis Risk Factors

Health History

Have you experienced any of the following at 40 years of age or older?

10. Fracture/Broken bone    Yes    No

   If yes, which bone(s)    Age

11. Marked decrease in height    Yes    No

   If “YES”, please specify how much your height decreased: _______ inches

12. Have you ever been diagnosed with osteoporosis?    Yes    No

   If “YES”:    Age at diagnosis:

   Where were you 1st diagnosed? ________________________

   How were you diagnosed (check all that apply):
   ___ Fracture/Broken bone, which bone(s) ________________________
   ___ Bone density scan. Where was the test performed:__________

   Specify type of test: ________________________

   Results (T-score, if known): ________

   ___ Other specify: ________________________

13. How many times have you fallen and landed on the floor or ground in the past 3 months (Do not include falls due to sport activities such as skiing, or those not from standing height).

   ___ none
   ___ 1 time
   ___ 2 times
   ___ 3 or more times
**Family History**

14. Do you have any family members (parents, grandparents, maternal aunt, full-blooded brothers or sisters, etc.) who have been diagnosed with or suspected to have osteoporosis? Full-blooded brothers and sisters are those who have the same two parents as you.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relationship of family member</td>
<td>Age diagnosed</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15. Do you have any family members (parents, grandparents, maternal aunt, full-blooded brothers or sisters, etc.) who have suffered a fracture/broken bone(s)?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relationship of family member</td>
<td>Age broken bone</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16. Have you ever been diagnosed and/or treated by a health care provider for any of the following: **Circle Yes or No** and if “YES” fill in the age at which you were newly diagnosed and/or treated.

<table>
<thead>
<tr>
<th>AGE</th>
<th>Kidney/ Renal problems</th>
<th>Heart disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes _____</td>
<td>No</td>
</tr>
</tbody>
</table>

| Parathyroid disease (e.g. hyperparathyroidism) | Diabetes |
| No  | Yes _____              | No           |

| Thyroid disease (e.g. hyperthyroidism) | Osteoarthritis |
| No  | Yes _____              | No           |

| Pituitary gland problem | Multiple sclerosis |
| No  | Yes _____              | No           |

| Adrenal gland problem | Rheumatoid arthritis |
| No  | Yes _____              | No           |

| Ovary problem | Autoimmune disease |
| No  | Yes _____              | No           |

| Testicular problem | Depression |
| No  | Yes _____              | No           |

| Stomach/Intestinal/Bowel problem | Bone disease |
| No  | Yes _____              | No           |

| Premature menopause (< 45 years) | other than osteoporosis |
| No  | Yes _____              | No           |
If you have circled **YES** please specify details including type of problem and treatment (if any):

---

---

17. Are you currently post-menopause (i.e. you have not had a menstrual cycle for 12 consecutive months)?  **Yes**  **No**  **Not Applicable**

If “YES”, how old were you when you had your last menstrual cycle? ________ years

**Diet and Nutrition**

18. Do you follow a special diet?  **Yes**  **No**

If “YES” please specify what kind of diet:

____ Vegetarian, specify type: ____________________________

____ Other: ____________________________

19. Do you have any **food allergies**? If yes, what are they?

---

---

20. Do you routinely consume any of the following **calcium-fortified foods**?

____ Calcium-fortified orange juice

____ Other types of fruit juice/beverages with added calcium, specify: ____________________________

____ Calcium-fortified soy beverages

____ Breads with calcium

____ Cereals with calcium

____ Waffles with calcium

____ Energy bars with calcium

____ Other calcium-fortified products, specify: ____________________________

21. Do you consume any of the following **caffeinated beverages**? If “YES”, also fill in the average amount consumed per day or per week.

<table>
<thead>
<tr>
<th>Beverage</th>
<th># of cups/day</th>
<th>OR</th>
<th># of cups/week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coffee, caffeinated</td>
<td>No</td>
<td>Yes</td>
<td>__________</td>
</tr>
<tr>
<td>Coffee, decaffeinated</td>
<td>No</td>
<td>Yes</td>
<td>__________</td>
</tr>
<tr>
<td>Tea, caffeinated</td>
<td>No</td>
<td>Yes</td>
<td>__________</td>
</tr>
<tr>
<td>Tea, decaffeinated</td>
<td>No</td>
<td>Yes</td>
<td>__________</td>
</tr>
<tr>
<td>Pop/carbonated beverage, caffeinated</td>
<td>No</td>
<td>Yes</td>
<td>__________</td>
</tr>
<tr>
<td>Pop/carbonated beverage, decaffeinated</td>
<td>No</td>
<td>Yes</td>
<td>__________</td>
</tr>
<tr>
<td>Other (specify_____________________________)</td>
<td>No</td>
<td>Yes</td>
<td>__________</td>
</tr>
</tbody>
</table>
Physical Activity

22. Do you perform any weight-bearing or muscle resistance exercise (e.g. lifting weights, walking, running, aerobics)  Yes  No

   If “YES”, how long have you been performing the exercise(s)? _______ years _______ months

   How often do you perform this exercise? _____ days/week OR _____ days/month

23. Do you perform any exercise to increase your balance or coordination?  Yes  No

   What type? _____ Tai Chi
   _____ Yoga
   _____ Pilates
   _____ Other, specify ________________________________

Tobacco Use

24. Do you currently smoke cigarettes?  Yes  No

   If “YES”, how many years have you smoked? _______ years

   How many cigarettes do you currently smoke each day?

   _____ less than 5
   _____ 5 to 15
   _____ 15 to 24
   _____ 25 or more

25. If you do not currently smoke cigarettes, have you ever smoked cigarettes?  Yes  No

   If “YES”, how many years did you smoke? _______ years

   What age did you stop smoking? _______ years

Alcohol Consumption

26. During the past 12 months, how often have you consumed any kind of alcoholic beverage? Assume that one drink is one can of beer, one 4 oz. glass of wine, or one shot of liquor.

   _____ 3 or more drinks a day
   _____ 2 drinks a day
   _____ One drink a day
   _____ 3 or 4 drinks a week
   _____ 1 or 2 drinks a week
   _____ 2 or 3 drinks a month
   _____ Once a month or less, but at least once in the past 12 months
   _____ Never in the past 12 months
Part III. Routine Medical Care

27. Have you ever received osteoporosis education?       Yes     No
   If “YES”, in what form did you receive this information? (check all that apply)
   _____ Pamphlets or booklets
   _____ Community talk
   _____ Online websites
   _____ Discussion with your doctor
   _____ Discussion with your pharmacist
   _____ Other: ____________________________________________

28. Do you have a regular medical check-up even when you are not sick?       Yes     No

29. Over the past 12 months have you been hospitalized?       Yes     No
   If “YES” what was the reason for hospitalization? (leave blank if you do not wish to answer)

30. Over the past 12 months how often did you visit a Family Doctor or General Practitioner?
   _____ Never
   _____ More than once a year
   _____ Once a year
   _____ Less than once a year \rightarrow Approximately how often? Every _____ years
       When was your last visit?      _____/______
       month       year

   i.)     What was their gender? _____ Male
            _____ Female

   ii.)    How many years have you been seeing the same Family Doctor or General Practitioner?
            _____ years

31. Over the past 12 months how often did you visit a Gynecologist?
   _____ Not applicable (male)
   _____ Never
   _____ More than once a year
   _____ Once a year
   _____ Less than once a year \rightarrow Approximately how often? Every _____ years
       When was your last visit?      _____/______
       month       year

   i.)     What was their gender? _____ Male
            _____ Female
32. Over the past 12 months how often did you visit an Orthopedic Doctor?

_____ Never
_____ More than once a year
_____ Once a year
_____ Less than once a year → Approximately how often? Every _____ years
When was your last visit? _____ / _____ month year

i.) What was their gender? _____ Male
_______ Female

33. Over the past 12 months how often did you visit a Nurse Practitioner?

_____ Never
_____ More than once a year
_____ Once a year
_____ Less than once a year → Approximately how often? Every _____ years
When was your last visit? _____ / _____ month year

i.) What was their gender? _____ Male
_______ Female

34. Over the past 12 months how often did you visit any other Health Care Provider (e.g. radiologist, etc.)? Specify type of provider: __________________________

_____ Never
_____ More than once a year
_____ Once a year
_____ Less than once a year → Approximately how often? Every _____ years
When was your last visit? _____ / _____ month year

i.) What was their gender? _____ Male
_______ Female

Part IV. Medication or Therapies

35. Are you taking any of the following prescription medications/therapies?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Taking</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics (Penicillin, tetracycline, etc.)</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Anticoagulants (Blood thinners)</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Antidepressants</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Anticholesterol Pills</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Diuretics</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Glucocorticoids (Cortisone, prednisone, etc.)</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Thyroid Pills</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Parathyroid Hormone/Forteo (PTH)</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Last taken (month/year)
Growth Hormone
Cox-2 Inhibitors (Celebrex, Vioxx)
Estrogen
Progesterone
Testosterone
Tamoxifen
Fosamax
Dirocal
Actonel
Aclasta
Evista
Miacalcin
Other, specify: 

36. The following questions relate to your health beliefs and osteoporosis drug treatment. Indicate how strongly you agree or disagree by checking (✓) the appropriate statement.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Drug treatments can help to build strong bones</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. You would feel good about taking drug treatments to prevent osteoporosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Drug treatments can cut down the chances of broken bones</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. You would consider taking drug treatments to prevent broken bones</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. If your doctor advised you to, you would take drug treatments to prevent broken bones</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Osteoporosis drug treatments would cost too much</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. You feel you already take too many medications to begin taking another drug</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Stomach problems would limit your ability to take osteoporosis drug treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. You are concerned about side effects of osteoporosis drug treatments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ID Number: ____________________

**CURRENT MEDICATIONS AND SUPPLEMENTS**

To help us evaluate the different factors associated with osteoporosis, we would like you to fill out the chart below. The following types of medications and supplements *taken within the last 3 months* should be included:

- Prescription medications
- Over-the-counter medications you take on a regular basis (4 or more times a month)
- Hormone medications
- Vitamins and Minerals (please specify exact name and brand)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Amount</th>
<th>Units</th>
<th>How often</th>
<th>How long have you been taking this</th>
<th>Reason for taking</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Example: Centrum Select 50+ (multivitamin)</em></td>
<td>1</td>
<td>tablet</td>
<td>Twice a day</td>
<td>6 years</td>
<td>General health</td>
</tr>
<tr>
<td><em>Example: Celebrex</em></td>
<td>200</td>
<td>mg</td>
<td>Once a day</td>
<td>3 months</td>
<td>Arthritis pain</td>
</tr>
</tbody>
</table>

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX H

3-Day Food Record

INSTRUCTIONS FOR KEEPING 3-DAY FOOD INTAKE RECORDS

A. A COMPLETE AND ACCURATE FOOD RECORD IS ESSENTIAL. PLEASE RECORD YOUR 24-HOUR FOOD and DRINK INTAKE FOR 2 TYPICAL WEEKDAYS (Monday to Friday) AND 1 WEEKEND DAY (Saturday or Sunday).

1. On the forms provided, record ALL the food and drink you have consumed.

2. It is easiest to record DIRECTLY after a meal or snack.

3. Include the TIME OF DAY when the food was eaten.

4. DESCRIBE the foods accurately. Give BRAND NAMES if possible. (E.g., Becel margarine, 1 teaspoon)

5. State whether fruits and vegetables were raw, canned, cooked or frozen.

6a. Record the AMOUNT of food eaten/serving size by using household measures such as cups, teaspoons, tablespoons, etc.

   For example: 2% milk, ½ cup (C)
   White sugar, 2 Tablespoons (tbsp)

6b. If the AMOUNT of food/serving size is difficult to describe, compare the amount of food eaten to the size or shape of a familiar object.

   For example: “the size of a tennis ball”
   “As thick as a pencil”

6c. TIPS ON ESTIMATING SERVING SIZE

   Source: Dairy Bureau of Canada, 1994

   A THUMB = 25 g of most cheeses
   A THUMB TIP = a teaspoon (tsp)
   THREE THUMB TIPS = A tablespoon (tbsp)…about the amount of milk that you would put in tea or coffee.
   A PALM = a serving of meat, fish or poultry. That’s without fingers and thumb!
   A FIST = 1 cup. A fist would be 1 1/3 servings of yogurt. A fist size of raw leafy greens would be a serving of lettuce.

6d. For meat, it is sometimes easier to give the measurements of a piece of cooked meat.

   For example: pork chops 3 ¼" x 2 ½" x ½" thick

7. Describe sandwiches in detail.

   For example: Ham sandwich = Whole white bread 2 slices
   Schneider’s ham 1 slice
   Kraft mayonnaise light 1 tsp.
   Lettuce 1 leaf
8. Be sure to record amounts of additional food served with cereals or desserts, etc.
   *For example:* Rice Krispies ½ cup
   2% milk 1/4 cup
   Brown sugar 2 level teaspoons

9. For MIXED such as casseroles, stews and baked goods e.g., homemade cookies, cakes, pies, and other desserts, please use the attached RECIPE forms. Provide the AMOUNT of ingredients in the recipe, the NUMBER of SERVINGS made and the PORTION that you ate.

10. Include HOW foods, such as meats fish, poultry, eggs, and vegetables, were prepared. The methods of preparation would include boiling, roasting, baking, frying, or steaming. When frying, specify the type and amount of fat or oil used.

11. Report the amount of water and any other fluid you drank in the whole day

12. Report your alcohol intake for the day

13. If you take vitamins/mineral supplements, please provide Brand name and amount of vitamin and/or mineral supplements taken each day.
3-Day Food Record – SAMPLE ONLY

Day 1: Monday

<table>
<thead>
<tr>
<th>Meal</th>
<th>Time</th>
<th>Place</th>
<th>Food</th>
<th>Preparation</th>
<th>Serving size</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>8 am</td>
<td>H</td>
<td>Cheerios</td>
<td></td>
<td>1.5 cups</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skim milk</td>
<td></td>
<td>1 cup</td>
</tr>
<tr>
<td>L</td>
<td>12 pm</td>
<td>H</td>
<td>Chicken breast, skinless</td>
<td>Grilled with salt &amp; pepper</td>
<td>1 medium breast (4 oz)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Green leaf lettuce</td>
<td>Salad</td>
<td>4 cups</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cherry tomatoes</td>
<td>In salad</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cucumber</td>
<td>In salad</td>
<td>½ cup</td>
</tr>
<tr>
<td>S</td>
<td>3 pm</td>
<td>H</td>
<td>Strawberry yogurt, Danone Activia</td>
<td></td>
<td>6 oz container</td>
</tr>
<tr>
<td>D</td>
<td>6 pm</td>
<td>H</td>
<td>Salmon</td>
<td>Baked</td>
<td>1 fillet (5 oz)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sweet potato</td>
<td>Baked</td>
<td>1 medium</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Becel butter</td>
<td>On potato</td>
<td>1 tbsp</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Broccoli, frozen</td>
<td>Steamed</td>
<td>1 cup</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Chocolate milk, 1%</td>
<td></td>
<td>3 cups</td>
</tr>
</tbody>
</table>
ID Number: ________________

3-Day Food Record

Weekday 1: ________________

<table>
<thead>
<tr>
<th>Meal</th>
<th>Time</th>
<th>Place</th>
<th>Food</th>
<th>Preparation</th>
<th>Serving size</th>
</tr>
</thead>
<tbody>
<tr>
<td>B Breakfast</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L Lunch</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D Dinner</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S Snack</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>H Home</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R Restaurant (list name)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Page 4 of 6
### 3-Day Food Record

**Weekday 2:**

<table>
<thead>
<tr>
<th>Meal</th>
<th>Time</th>
<th>Place</th>
<th>Food</th>
<th>Preparation</th>
<th>Serving size</th>
</tr>
</thead>
<tbody>
<tr>
<td>B Breakfast</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L Lunch</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D Dinner</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S Snack</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>H Home</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R Restaurant (list name)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>How did you cook it? What did you add to it?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3-Day Food Record

Weekend 1: ________________

<table>
<thead>
<tr>
<th>Meal</th>
<th>Time</th>
<th>Place</th>
<th>Food</th>
<th>Preparation</th>
<th>Serving size</th>
</tr>
</thead>
<tbody>
<tr>
<td>B Breakfast</td>
<td>H Home</td>
<td>(be very specific, include name brands)</td>
<td>How did you cook it? What did you add to it?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L Lunch</td>
<td>R Restaurant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D Dinner</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S Snack</td>
<td>O Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Page 6 of 6
INSTRUCTIONS FOR COMPLETION:
The Modified Baecke Questionnaire for Older Adults
(from Voorrips et al., 1991)

The Modified Baecke Questionnaire for Older Adults assesses habitual physical activity, including household, sport, and leisure activity. The type of sport and leisure activities performed will be listed and coded according to intensity of the activity performed, hours per week spent performing the activity, and number of months per year the activity is typically performed.

INSTRUCTIONS FOR CODING SPORT AND LEISURE ACTIVITY:

<table>
<thead>
<tr>
<th>Codes for the Modified Baecke Questionnaire</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensity code†</td>
<td>Code</td>
</tr>
<tr>
<td>0: Lying, unloaded</td>
<td>0.028</td>
</tr>
<tr>
<td>1: Sitting, unloaded</td>
<td>0.146</td>
</tr>
<tr>
<td>2: Sitting, hand or arm movements</td>
<td>0.297</td>
</tr>
<tr>
<td>3: Sitting, body movements</td>
<td>0.703</td>
</tr>
<tr>
<td>4: Standing, unloaded</td>
<td>0.174</td>
</tr>
<tr>
<td>5: Standing, hand or arm movements</td>
<td>0.307</td>
</tr>
<tr>
<td>6: Standing, body movements, walking</td>
<td>0.890</td>
</tr>
<tr>
<td>7: Walking, hand or arm movements</td>
<td>1.368</td>
</tr>
<tr>
<td>8: Walking, body movements, cycling, swimming</td>
<td>1.890</td>
</tr>
</tbody>
</table>

Hours per week:

1. Less than 1 h/wk                                             | Code 0.5
2. 1 - < 2 h/wk                                                 | Code 1.5
3. 2 - < 3 h/wk                                                 | Code 2.5
4. 3 - < 4 h/wk                                                 | Code 3.5
5. 4 - < 5 h/wk                                                 | Code 4.5
6. 5 - < 6 h/wk                                                 | Code 5.5
7. 6 - < 7 h/wk                                                 | Code 6.5
8. 7 - < 8 h/wk                                                 | Code 7.5
9. 8 or more h/wk                                               | Code 8.5

Months per year:

1. Less than 1 mo/yr                                            | Code 0.04
2. 1-3 mo/yr                                                    | Code 0.17
3. 4-6 mo/yr                                                    | Code 0.42
4. 7-9 mo/yr                                                    | Code 0.67
5. More than 9 months/yr                                         | Code 0.92

† Unitless intensity code, originally based on energy costs.
CODING EXAMPLES:

SPORT ACTIVITIES (see instructions for codes)
Do you take part in any sport activities (e.g. swimming, walking, cycling, aerobics, weight-lifting, etc.)? You may list up to 6 activities.

Sport 1:  Name: Bowling  
Intensity (code): The code is 0.890 (from no. 6: standing, body movements, walking)  
Hours per week (code): 1-2 h/wk. This would be coded as 1.5  
Months per year (code): 6 mo/yr. This would be coded as 0.42

Sport 2:  Name: Swimming  
Intensity (code): 1.890.  
Hours per week (code): 2-3 h/wk. This would be coded as 2.5.  
Months per year (code): 10 mo/yr. This would be coded as 0.92

LEISURE ACTIVITIES (Note: Instructions are the same as sport activities, using the same codes for intensity and duration)
Do you take part in any leisure activities (e.g. gardening, sewing, reading, writing, etc.)? You may list up to 6 activities

Activity 1:  Name: Knitting  
Intensity (code): 0.297 (from #2: sitting, movements of hand or arm)  
Hours per week (code): 10 h/wk. This would be coded as 8.5  
Months per year (code): 12 mo/yr. This would be coded as 0.92
Modified Baecke Questionnaire for Older Adults
(from Voorrips et al., 1991)

HOUSEHOLD ACTIVITIES

Answer the following 10 questions by circling the response that best describes your household activity. Questions 3 and 5 require a numerical answer.

1.) Do you do the light household work? (dusting, washing dishes, repairing clothes, etc.)?
   0. Never (< once a month)
   1. Sometimes (only when partner or help is not available)
   2. Mostly (sometimes assisted by partner or help)
   3. Always (alone or together with partner)

2.) Do you do the heavy housework? (washing floors and windows, carrying trash disposal bags, etc.)?
   0. Never (< once a month)
   1. Sometimes (only when partner or help is not available)
   2. Mostly (sometimes assisted by partner or help)
   3. Always (alone or together with partner)

3.) For how many persons do you keep house? (including yourself; fill in “0” if you answered “never” in Q1 and Q2.)
   __________

4.) How many rooms do you keep clean, including kitchen, bedroom, garage, cellar, bathroom, ceiling, etc.? (fill in “0” if you answered “never” in Q1 and Q2.)
   0. Never do housekeeping
   1. 1-6 rooms
   2. 7-9 rooms
   3. 10 or more rooms
   __________

5.) If any rooms, on how many floors? (fill in “0” if you answered “never” in Q4.)
   __________
6.) Do you prepare warm meals yourself, or do you assist in preparing?
0. Never
1. Sometimes (once or twice a week)
2. Mostly (3-5 times a week)
3. Always (more than 5 times a week)

7.) How many flights of stairs do you walk up per day? (one flight of stairs is 10 steps.)
0. I never walk stairs
1. 1-5
2. 6-10
3. More than 10

8.) If you go somewhere in your hometown, what kind of transportation do you use?
0. I never go out
1. Car
2. Public transportation
3. Bicycle
4. Walking

9.) How often do you go out for shopping?
0. Never or less than once a week
1. Once a week
2. Twice to four times a week
3. Every day

10.) If you go out for shopping, what kind of transportation do you use?
0. I never go out
1. Car
2. Public transportation
3. Bicycle
4. Walking
ID Number:__________________________

SPORT ACTIVITIES
Do you take part in any sport activities (e.g. swimming, walking, cycling, aerobics, weight-lifting, etc.)? You may list up to 6 activities. Information should be recorded as type of activity, intensity that the activity was normally performed, duration (hours per week), and frequency (number of months per year). Please refer to the coding instructions on page 1.

Sport 1: Name:__________________________
Intensity (code):________________________
Hours per week (code):__________________
Months per year (code):__________________

Sport 2: Name:__________________________
Intensity (code):________________________
Hours per week (code):__________________
Months per year (code):__________________
LEISURE ACTIVITIES

Do you take part in any leisure activities (e.g. gardening, sewing, reading, writing, etc.)? You may list up to 6 activities. Instructions for recording codes are the same as sport activities. Please refer to the coding instructions on page 1.

Activity 1: Name: ____________________________
  Intensity (code): ____________________________
  Hours per week (code): ______________________
  Months per year (code): ______________________

Activity 2: Name: ____________________________
  Intensity (code): ____________________________
  Hours per week (code): ______________________
  Months per year (code): ______________________

Activity 3: Name: ____________________________
  Intensity (code): ____________________________
  Hours per week (code): ______________________
  Months per year (code): ______________________

Activity 4: Name: ____________________________
  Intensity (code): ____________________________
  Hours per week (code): ______________________
  Months per year (code): ______________________

Activity 5: Name: ____________________________
  Intensity (code): ____________________________
  Hours per week (code): ______________________
  Months per year (code): ______________________

Activity 6: Name: ____________________________
  Intensity (code): ____________________________
  Hours per week (code): ______________________
  Months per year (code): ______________________
APPENDIX J

ID Number: ________________

**The Osteoporosis Knowledge Test**  
*(from Kim, Horan, and Gendler, 1991)*

Osteoporosis is a disease in which the bones become very brittle and weak causing them to fracture easily. Below is a list of things that may or may not affect a person’s chance of getting osteoporosis. After reading each one, indicate whether you think a person is:

- **MORE LIKELY TO GET OSTEOPOROSIS,**
- **LESS LIKELY TO GET OSTEOPOROSIS,**
- **IT HAS NOTHING TO DO WITH GETTING OSTEOPOROSIS (NEUTRAL),** or
- **DON’T KNOW.**

<table>
<thead>
<tr>
<th></th>
<th><strong>More Likely</strong></th>
<th><strong>Less Likely</strong></th>
<th><strong>Neutral</strong></th>
<th><strong>Don’t Know</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Eating a diet low in milk products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Being menopausal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Having big bones</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Eating a diet high in dark leafy vegetables</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Having a mother or grandmother who has osteoporosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Being a white woman with fair skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Having ovaries surgically removed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Taking cortisone (steroids, e.g. Prednisone) for long time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Exercising on a regular basis</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
For the next group of questions, you will be asked to choose one answer from several choices. Be sure to choose only one answer. If you are not sure, just choose “I don’t know.”

10. Which of the following exercises is the best way to reduce a person’s chance of getting osteoporosis?
   A. Swimming
   B. Walking briskly
   C. Doing kitchen chores, such as washing dishes or cooking
   D. Don’t know

11. Which of the following exercises is the best way to reduce a person’s chance of getting osteoporosis?
   A. Bicycling
   B. Yoga
   C. Housecleaning
   D. Don’t know

12. How many days a week do you think a person should exercise to strengthen the bones?
   A. 1 day a week
   B. 2 days a week
   C. 3 or more days a week
   D. Don’t know

13. What is the least amount of time a person should exercise on each occasion to strengthen the bones?
   A. Less than 15 minutes
   B. 20 to 30 minutes
   C. More than 45 minutes
   D. Don’t know

14. Exercise makes bones strong, but it must be hard enough to make breathing:
   A. Just a little faster
   B. So fast that talking is not possible
   C. Much faster, but talking is possible
   D. Don’t know
15. Which of the following exercises is the best way to reduce a person’s chance of getting osteoporosis?
   A. Jogging, running, or walking for exercise
   B. Golfing using golf cart
   C. Gardening
   D. Don’t know

16. Which of the following exercises is the best way to reduce a person’s chance of getting osteoporosis?
   A. Bowling
   B. Doing laundry
   C. Aerobic dancing
   D. Don’t know

17. Which of these is a good source of calcium?
   A. Apple
   B. Cheese
   C. Cucumber
   D. Don’t know

18. Which of these is a good source of calcium?
   A. Watermelon
   B. Corn
   C. Canned sardines
   D. Don’t know

19. Which of these is a good source of calcium?
   A. Chicken
   B. Broccoli
   C. Grapes
   D. Don’t know
20. Which of these is a good source of calcium?
   A. Yogurt  
   B. Strawberries  
   C. Cabbage  
   D. Don’t know

21. Which of these is a good source of calcium?
   A. Ice cream  
   B. Grapefruit  
   C. Radishes  
   D. Don’t know

22. Which of the following is the recommended amount of calcium intake for an adult?
   A. 100 mg – 300 mg daily  
   B. 400 mg – 600 mg daily  
   C. 1200 mg – 1500 mg daily  
   D. Don’t know

23. How much milk must an adult drink to meet the recommended amount of calcium?
   A. ½ glass daily  
   B. 1 glass daily  
   C. 4 or more glasses daily  
   D. Don’t know

24. Which of the following is the best reason for taking a calcium supplement?
   A. If a person skips breakfast  
   B. If a person does not get enough calcium from diet  
   C. If a person is over 45 years old  
   D. Don’t know
APPENDIX K

ID Number: ____________________

The Osteoporosis Health Belief Scale Questionnaire
(from Kim et al., 1991)

The Osteoporosis Health Belief Scale is a 35-item scale designed to measure general health motivation, perceived susceptibility to and seriousness of osteoporosis, and beliefs about calcium intake and exercise in preventing and managing osteoporosis. Please indicate how strongly you agree or disagree by checking (✓) the appropriate statement.

<table>
<thead>
<tr>
<th>A.</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Your chances of getting osteoporosis in the future are high</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. It is extremely likely that you will get osteoporosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Your physical health makes it more likely that you will get osteoporosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. There is a good chance that you will get osteoporosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Your family history makes it more likely that you will get osteoporosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B.</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. The thought of having osteoporosis scares you</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. If you had osteoporosis your whole life would change</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Your feelings about yourself would change if you got osteoporosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Having osteoporosis would make daily activities more difficult</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Osteoporosis would endanger your marriage or a significant relationship</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>Disagree</td>
<td>Neither agree nor disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
</tr>
<tr>
<td>---</td>
<td>-------------------</td>
<td>----------</td>
<td>---------------------------</td>
<td>-------</td>
<td>----------------</td>
</tr>
<tr>
<td>11.</td>
<td>Regular exercise prevents future problems that would happen from osteoporosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>You would not be so anxious about osteoporosis if you exercise regularly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Regular exercise helps to build strong bones</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Exercising regularly prevents future pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>Exercising regularly reduces risk of broken bones</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>Disagree</td>
<td>Neither agree nor disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
</tr>
<tr>
<td>16.</td>
<td>You feel like you are not strong enough to exercise regularly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17.</td>
<td>Exercising regularly would mean starting a new habit which is hard for you to do</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18.</td>
<td>Exercising regularly can be painful</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19.</td>
<td>Exercising regularly upsets your every day routine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20.</td>
<td>Exercising regularly can be time consuming</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E.</td>
<td>Strongly disagree</td>
<td>Disagree</td>
<td>Neither agree nor disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
</tr>
<tr>
<td>----</td>
<td>------------------</td>
<td>---------</td>
<td>---------------------------</td>
<td>-------</td>
<td>---------------</td>
</tr>
<tr>
<td>21. Taking in <strong>enough</strong> calcium prevents future problems from osteoporosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. Taking in <strong>enough</strong> calcium cuts down on your chances of broken bones</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23. You would not worry as much about osteoporosis if you took in <strong>enough</strong> calcium</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24. Taking in <strong>enough</strong> calcium prevents painful osteoporosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25. Eating calcium rich foods helps to build bones</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F.</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>26. Eating calcium rich foods requires changing your diet which is hard to do</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27. You feel you will not be able to always eat calcium rich foods</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28. Calcium rich foods cost too much</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29. Calcium rich foods do not agree with you</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. You do not like calcium rich foods</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>Disagree</td>
<td>Neither agree nor disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
</tr>
<tr>
<td>---</td>
<td>------------------</td>
<td>----------</td>
<td>---------------------------</td>
<td>-------</td>
<td>----------------</td>
</tr>
<tr>
<td>31. You eat a well-balanced diet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32. You exercise regularly – at least three times a week</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33. You look for new information related to your health</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34. Keeping healthy is very important for you</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35. You frequently do things to improve your health</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Osteoporosis Self-Efficacy Scale Questionnaire
(from Horan et al., 1998)

The Osteoporosis Self-Efficacy Scale is a 21-item scale that measures confidence in performing health behaviours related to exercise and calcium intake. Circle the number (0 = least confident, 10 = most confident) that best indicates your confidence in performing the following health behaviours. The phrase “If it were recommended that you do any of the following this week, how confident would you be that you could…” should be used as a precursor for each item.

1. Begin a new or different exercise program

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Change your exercise habits

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Put forth the effort required to exercise

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Do exercises even if they are difficult

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Maintain a regular exercise program

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. Exercise for the appropriate length of time

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7. Do exercises even if they are tiring

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. Stick to your exercise program

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Exercise at least three times a week

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. Do the type of exercises you are supposed to do

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. Begin to eat more calcium-rich foods

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12. Increase your calcium intake

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

13. Consume adequate amounts of calcium-rich foods

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

14. Eat calcium-rich foods on a regular basis

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>least confident</td>
<td>very confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
15. Change your diet to include more calcium-rich foods

0  1  2  3  4  5  6  7  8  9  10
least very confident

16. Eat calcium-rich foods as often as you are supposed to

0  1  2  3  4  5  6  7  8  9  10
least very confident

17. Select appropriate foods to increase your calcium intake

0  1  2  3  4  5  6  7  8  9  10
least very confident

18. Stick to a diet which gives an adequate amount of calcium

0  1  2  3  4  5  6  7  8  9  10
least very confident

19. Obtain foods that give an adequate amount of calcium

0  1  2  3  4  5  6  7  8  9  10
least very confident

20. Remember to eat calcium-rich foods

0  1  2  3  4  5  6  7  8  9  10
least very confident

21. Take calcium supplements if you don’t get enough calcium from your diet

0  1  2  3  4  5  6  7  8  9  10
least very confident
APPENDIX M

February 1, 2011

Dear XXXXXXXXXXX,

Thank you for your continued participation in our “Healthy Bones” research study. We are looking forward to seeing you for your final study visit on ________________ at ____________.

Enclosed you will find:

➢ A follow-up questionnaire, 3-day food diary, and physical activity questionnaire for you to complete and bring to your appointment. Please follow all instructions provided with the questionnaires.
➢ A parking pass and directions to the parking location and our lab at the University of Regina.

Please bring with you:

✓ All the completed questionnaires that were mailed in your package
✓ The same attire you wore at your first visit for the body composition assessment in the Bod pod (e.g. Women: a bathing suit or spandex shorts and sports bra or shorts and tank top if you do not own a bathing suit; Men: gym shorts or spandex shorts). You may wear these garments under your clothes or change into them prior to the test.
✓ The parking pass. On the day of your visit, place the pass visible in your rearview mirror.

The entire visit will take no more than 30 minutes. If you cannot keep your appointment and need to reschedule or if you have any questions, please call Katherine McLeod at 337-3329 (emergency contact: 581-5423). Thank you again for your continued interest and support of this important study. We look forward to seeing you soon.

Sincerely,

Katherine McLeod, PhD candidate, MSc
Faculty of Kinesiology and Health Studies
University of Regina
APPENDIX N

ID Number: ____________________

Bone Health Research Study
FOLLOW-UP QUESTIONNAIRE

Below you will find a number of questions regarding your health since your bone density screening at the Regina General Hospital and participation in the “Bone Health” research study. The exact date of your study visit can be found in your cover letter. Please answer all questions to the best of your ability. If you are uncertain about the timing of any of the information you may be helped by:

- Checking your own records
- Checking with your doctor
- Asking a family member or friend

If you are still somewhat uncertain, answer to the best of your memory and provide a written note in the margin, if possible. If you have any questions please feel free to call the primary investigator.

Today’s Date: __/__/__

Month Day Year

1. Since your study visit, have you suffered a fracture/broken bone
   Yes  No

<table>
<thead>
<tr>
<th>If “YES”, which bone(s)</th>
<th>Date of broken bone</th>
<th>How did it happen?</th>
<th>How was it treated?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>/</strong>/__</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>month year</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>/</strong>/__</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>month year</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>/</strong>/__</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>month year</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Have you been hospitalized since you participated in this study?
   _____ No
   _____ Yes, explain: ____________________________________________

3. Have you been diagnosed with any new illness since you participated in this study?
   _____ No
   _____ Yes, explain: ____________________________________________

4. Did you talk to or meet with your health care provider to discuss your recent bone density screening results?
   _____ No → If “No” proceed to question 19.
   _____ Yes → When did you first discuss this with him/her? __/__/__
   month year
5. Which of the following health care providers did you talk to or meet with to discuss your bone density screening results? (Circle the gender of each health care provider)

   Male or Female  Family Doctor/General Practitioner
   Male or Female  Gynecologist
   Male or Female  Orthopedic Doctor
   Male or Female  Nurse Practitioner
   Male or Female  Nutritionist/Dietitian
   Male or Female  Pharmacist
   Male or Female  Other, specify whom: ________________________________

6. Which one health care provider did you mainly discuss your bone density screening results with?
   _____ Family Doctor/General Practitioner
   _____ Gynecologist
   _____ Orthopedic Doctor
   _____ Nurse Practitioner
   _____ Nutritionist/Dietitian
   _____ Pharmacist
   _____ Other, specify whom: ________________________________

7. How many years have you known this person? ______ years

8. After discussing your bone density screening results with your health care provider (e.g. family doctor), what did he/she tell you about the results? (Check √ one)
   _____ You have osteoporosis
   _____ You have osteopenia (moderate bone loss)
   _____ You have normal bones
   _____ My doctor did not provide a specific diagnosis

9. After discussing your bone density screening results with your health care provider, did he/she discuss any of the following osteoporosis medications? (Check √ all that apply)
   _____ Fosamax
   _____ Didrocal
   _____ Actonel
   _____ Aclasta
   _____ Evista
   _____ Miacalcin
   _____ Forteo
   _____ Hormone Therapy
   _____ Other, specify: ________________________________
   _____ My doctor did not discuss any of these medications
10. *After discussing your bone density screening results with your health care provider, did he/she prescribe or continue to prescribe* any of the following osteoporosis medications? *(Check ✓ all that apply)*
   - Fosamax
   - Didrocal
   - Actonel
   - Aclasta
   - Evista
   - Miacalcin
   - Forteo
   - Hormone Therapy
   - Other, specify: __________________________
   - My doctor did not prescribe any medications

11. *After discussing your bone density screening results with your health care provider, did you actually take* any of these *prescribed or continued* osteoporosis medications? *(Check ✓ all that apply)*
   - Fosamax
   - Didrocal
   - Actonel
   - Aclasta
   - Evista
   - Miacalcin
   - Forteo
   - Hormone Therapy
   - Other, specify: __________________________
   - My doctor did not prescribe any medications
   - I chose not to take any medications

12. *After discussing your bone density screening results with your health care provider, what was the decision of whether to take or not to take* an osteoporosis medication based on? *(Check ✓ one)*
   - Based solely on a personal decision
   - Based on a joint decision with you and your doctor
   - Based solely on a recommendation from your doctor
   - My doctor never discussed taking any medication
13. After discussing your bone density screening results with your health care provider, what factors were used to decide whether to take or not to take an osteoporosis medication? (Check all that apply)
   - Potential benefits of taking the medication
   - Potential risks of taking the medication (e.g. side effects)
   - Administration (how the drug is taken)
   - Other health conditions I have
   - Other medications I currently take
   - Cost
   - Other, specify: ____________________________
   - My doctor never discussed taking any medication

14. After discussing your bone density screening results with your health care provider, where did you get the information that helped you make a decision whether to take or not to take an osteoporosis medication? (Check all that apply)
   - Your doctor
   - Pharmacist
   - Family
   - Friends
   - Television
   - Radio
   - Internet
   - Newspaper
   - Magazine
   - Book
   - Education materials/video from the “Bone Health” study
   - Other, specify: ____________________________

15. After discussing your bone density screening results with your health care provider, did he/she discuss any of the following lifestyle changes? (Check all that apply)
   - Start or increase calcium intake
   - Start or increase vitamin D intake
   - Start or increase other vitamin or mineral intake, specify: ____________________________
   - Start or increase weight bearing exercise, specify: ____________________________
   - Start or increase other exercise, specify: ____________________________
   - Stop smoking
   - Reduce caffeine intake
   - Other, specify: ____________________________
   - My doctor did not discuss any lifestyle changes
16. After discussing your bone density screening results with your health care provider, did he/she recommend any of the following lifestyle changes? (Check √ all that apply)

_____ Start or increase calcium intake
_____ Start or increase vitamin D intake
_____ Start or increase other vitamin or mineral intake, specify:__________________________
_____ Start or increase weight bearing exercise, specify:______________________________
_____ Start or increase other exercise, specify:_______________________________________
_____ Stop smoking
_____ Reduce caffeine intake
_____ Other, specify:____________________________________________________________
_____ My doctor did not recommend any lifestyle changes

17. After discussing your bone density screening results with your health care provider, did you follow your health care provider’s recommendation for any of the following lifestyle changes? (Check √ all that apply)

_____ Start or increase calcium intake
_____ Start or increase vitamin D intake
_____ Start or increase other vitamin or mineral intake, specify:__________________________
_____ Start or increase weight bearing exercise, specify:______________________________
_____ Start or increase other exercise, specify:_______________________________________
_____ Stop smoking
_____ Reduce caffeine intake
_____ Other, specify:____________________________________________________________
_____ My doctor did not recommend any lifestyle changes

18. After reviewing your bone density screening results and taking part in the “Bone Health” study, did you personally decide to make any of the following lifestyle changes? (Do not include changes that were recommended by your health care provider) (Check √ all that apply)

_____ Start or increase calcium intake
_____ Start or increase vitamin D intake
_____ Start or increase other vitamin or mineral intake, specify:__________________________
_____ Start or increase weight bearing exercise, specify:______________________________
_____ Start or increase other exercise, specify:_______________________________________
_____ Stop smoking
_____ Reduce caffeine intake
_____ Other, specify:____________________________________________________________
_____ I did not make any lifestyle changes based on a personal decision
19. If you made any lifestyle changes as a result of reviewing your bone density screening results and taking part in the “Bone Health” study, please indicate which of these changes you are currently maintaining. (Include changes based on a doctor’s recommendation as well as your own decision) (Check √ all that apply)

- Start or increase calcium intake
- Start or increase vitamin D intake
- Start or increase other vitamin or mineral intake, specify: _______________________
- Start or increase weight bearing exercise, specify: _______________________
- Start or increase other exercise, specify: _______________________
- Stop smoking
- Reduce caffeine intake
- Other, specify: ___________________________________________________________________
- I did not make any lifestyle changes

20. After discussing your bone density screening results with your health care provider, where did you get the information that helped you make a decision whether to make a lifestyle change (for example, start or increase calcium and/or vitamin D intake)? (Check √ all that apply)

- Your doctor
- Pharmacist
- Family
- Friends
- Television
- Radio
- Internet
- Newspaper
- Magazine
- Book
- Education materials/video from the “Bone Health” study
- Other, specify: __________________________________________________________________

21. After reviewing your bone density screening results, did your health care provider discuss when your next bone density screening test should be scheduled? (Check √ one)

- 1 year from your last screening
- 2 years from your last screening
- 3 years from your last screening
- 4 years from your last screening
- 5 years from your last screening
- My doctor did not discuss my next screening test
22. Do you currently consume any of the following calcium-fortified foods? (Check √ all that apply)
   ___ Calcium-fortified orange juice
   ___ Other types of fruit juice/beverages with added calcium, specify: __________
   ___ Calcium-fortified soy beverages
   ___ Breads with calcium
   ___ Cereals with calcium
   ___ Waffles with calcium
   ___ Energy bars with calcium
   ___ Other calcium-fortified products, specify: ________________________________

24. Do you currently take a calcium supplement?  Yes  No
   If “YES”, what is the brand of supplement (e.g. Caltrate): __________________________
   What is amount of calcium (e.g. 600 mg): ________________________________
   **NOTE: The milligrams (mg) can be found on the back of the bottle label.
   How often do you take the supplement (e.g. once a day): __________________________

25. Do you currently take a vitamin D supplement?  Yes  No
   If “YES”, what is the brand of supplement (e.g. Caltrate): __________________________
   What is amount of calcium (e.g. 400 IU): ________________________________
   **NOTE: The International Units (IU) can be found on the back of the bottle label.
   How often do you take the supplement (e.g. once a day): __________________________

26. Do you currently take a multivitamin that contains calcium and/or vitamin D?  Yes  No
   If “YES”, what is the brand of supplement (e.g. Centrum): __________________________
   What is amount of calcium (e.g. 175 mg): ________________________________
   What is amount of vitamin D (e.g. 400 IU): ________________________________
   **NOTE: The milligrams (mg) and International Units can be found on the back of the bottle label.
   How often do you take the supplement (e.g. twice a day): __________________________
APPENDIX O

REGINA QU’APPELLE HEALTH REGION
REGINA GENERAL HOSPITAL
1440 14th Avenue
Regina, SK.
S4P 0W5
Fax: (306) 766-4134

NURSING UNIT: OUT
NAME:
HIN #:
SHSP:
ACCT:
DOB :

BONE MINERAL DENSITOMETRY EXAM

PHYSICIAN:

EXAMINATION REQUESTED: BMD: BASELINE

DATE OF EXAM:

<table>
<thead>
<tr>
<th>Site</th>
<th>g/cm²</th>
<th>T-score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spine (L1 - L4)</td>
<td>1.022</td>
<td>-1.3</td>
</tr>
<tr>
<td>Left Femur (Neck)</td>
<td>0.876</td>
<td>-1.2</td>
</tr>
<tr>
<td>Right Femur (Neck)</td>
<td>0.773</td>
<td>-1.9</td>
</tr>
<tr>
<td>Left Forearm (radial 33%)</td>
<td>0.691</td>
<td>-2.2</td>
</tr>
</tbody>
</table>

Ten-year absolute fracture risk: LOW

Low (<10%) Moderate (10 - 20%) High (>20%)

REPORT:

The lowest site is the left radial 33% (T-score -2.2)(osteopenic). This patient’s fracture risk is low based on age and BMD (ten-year fracture risk <10%). Ensure adequate calcium and Vitamin D intake, and also physical exercise. Unlikely to benefit from pharmacotherapy. Repeat BMD in 3 - 5 years and reassess fracture risk.

The DXA bone mass measurement was made on a GE Lunar Prodigy (Version 10.51) instrument.

WORLD HEALTH ORGANIZATION CRITERIA

Normal: A value for BMD or BMC within 1 SD of the young adult reference mean.
Osteopenia: A value for BMD or BMC more than 1 SD below the young adult mean but less than 2.5 SD below this value.
Osteoporosis: A value for BMD or BMC 2.5 SD or more below the young adult mean.
Severe Osteoporosis: A value for BMD or BMC more than 2.5 SD below the young adult mean in the presence of one or more fragility fractures.

(Original signed)
### Subject Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Katherine_1 McLeod</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>31</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
</tr>
<tr>
<td>Height</td>
<td>66.9 in</td>
</tr>
<tr>
<td>ID_1</td>
<td></td>
</tr>
<tr>
<td>ID_2</td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td>General Population</td>
</tr>
<tr>
<td>Operator</td>
<td>sjlab1</td>
</tr>
<tr>
<td>Test Date</td>
<td>October 6, 2012</td>
</tr>
<tr>
<td>Test Number</td>
<td>088</td>
</tr>
</tbody>
</table>

### Body Composition Result

| % Fat            | 18.2 % |
| % Fat Free Mass  | 81.8 % |
| Fat Mass         | 21.300 lb |
| Fat Free Mass    | 90.023 lb |
| Body Mass        | 117.413 lb |
| Body Volume      | 50.376 L |
| Body Density     | 1.057 kg/L |
| Thoracic Gas Volume | 3.387 L |

### Test Profile

- **Density Model**: Siri
- **Thoracic Gas Volume Model**: Predicted

### Body Fat

- **Body Fat**: A certain amount of fat is absolutely necessary for good health. Fat plays an important role in protecting internal organs, providing energy, and regulating hormones. The minimal amount of "essential fat" is approximately 3-5% for men, and 12-15% for women. If too much fat accumulates over time, health may be compromised (see table below).

- **Fat Free Mass**: Fat free mass is everything except fat. It includes muscle, water, bone, and internal organs. Muscle is the "metabolic engine" of the body that burns calories (fat) and plays an important role in maintaining strength and energy. Healthy levels of fat-free mass contribute to physical fitness and may prevent conditions such as osteoporosis.

### LMI Body Fat Rating Table*

<table>
<thead>
<tr>
<th>Body Fat Rating</th>
<th>Female</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risky (high body fat)</td>
<td>&gt; 40%</td>
<td>Ask your health care professional about how to safely modify your body composition.</td>
</tr>
<tr>
<td>Excess Fat</td>
<td>30 - 40%</td>
<td>Indicates an excess accumulation of fat over time.</td>
</tr>
<tr>
<td>Moderately Lean</td>
<td>22 - 30%</td>
<td>Fat level is generally acceptable for good health.</td>
</tr>
<tr>
<td>Lean</td>
<td>18 - 22%</td>
<td>Lower body fat levels than many people. This range is generally excellent for health and longevity.</td>
</tr>
<tr>
<td>Ultra Lean</td>
<td>15 - 18%</td>
<td>Fat levels often found in elite athletes.</td>
</tr>
<tr>
<td>Risky (low body fat)</td>
<td>&lt; 15%</td>
<td>Ask your health care professional about how to safely modify your body composition.</td>
</tr>
</tbody>
</table>

### Energy Expenditure Results

<table>
<thead>
<tr>
<th>Est. Resting Metabolic Rate (RMR) kcal/day</th>
<th>*Est. Total Energy Expenditure (TEE) kcal/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1163</td>
<td></td>
</tr>
</tbody>
</table>

- Applies to adults ages 18 and older. Based on information from the American College of Sports Medicine, the American Council on Exercise, Exercise Physiology (4th Ed.) by McArdle, Katch, and Katch, and various scientific and epidemiological studies.

---

Achilles InSight
Ultrasound Results
University of Regina

ID
DATE
TIME
Version

STIFFNESS INDEX

AGE
SEX
FOOT

REFERENCE

% YOUNG ADULT
T SCORE

BUA
SOS

Image not for diagnosis

STIFFNESS INDEX

T

132
100
60
36
20 30 40 50 60 70 80 90 100
AGE (Years)

FRACTURE RISK


335
## APPENDIX R

### Theory-informed Osteoporosis Education Intervention Topics and Curriculum Sources

<table>
<thead>
<tr>
<th>RHBM Construct</th>
<th>Topic focus</th>
<th>Education Sources</th>
</tr>
</thead>
</table>
| Perceived susceptibility | - Describe osteoporosis, prevalence, and risk factors.  
                         - Tailor risk information to men and women over 50 years.  
                         - Help the individual develop an accurate perception of his or her own risk.                                                                 | - Video – “Osteoporosis: Meeting the Challenges”.  
                                                                         - Osteoporosis Canada Fact Sheets.                                                                            |
| Perceived seriousness | - Specify the consequences of osteoporosis and related fracture.                                                                                                                                              | - Video – “Osteoporosis: Meeting the Challenges”  
                                                                         - Osteoporosis Canada Fact Sheets.                                                                             |
| Perceived benefits   | - Explain the benefits of calcium and vitamin D intake, physical activity, and drug treatment.  
                         - Explain how, where, and when to engage in these health behaviours.                                                                                                                                         | - Video – “Osteoporosis: Meeting the Challenges”  
                                                                         - Osteoporosis Canada Fact Sheets.                                                                             |
| Perceived barriers   | - Information on overcoming barriers to reducing risk factors such as caffeine consumption, improving physical activity.  
                         - Correct misinformation and myths as they pertain to calcium and vitamin D intake.                                                                                                                     | - Facts and Myths summary document.  
                                                                         - Provide local sites and opportunities to engage in low-cost physical activity (e.g., mall-walking programs).                                                                 |
| Self-efficacy        | - Improve confidence in individual’s ability to engage in the health behaviour.                                                                                                                                 | - “Helping You Take Care of your Bones” Osteoporosis Canada brochure  
                                                                         - Explanation of how to choose a calcium and vitamin D supplement and when to take.  
                                                                         - Magnets  
                                                                         - Fitness pass to the Fitness and Lifestyle Centre, University of Regina and tour of facilities.                                                                 |

*Note.* Magnets listed daily requirements of calcium and vitamin D and calcium content of common foods; the “Helping You Take Care of your Bones” Osteoporosis Canada brochure provided resources and information for individual and group support; Osteoporosis Canada Fact Sheets: Diagnosis, Nutrition, Exercise for Healthy Bones, Drug Treatment, Men and Osteoporosis, Osteoporosis and Osteoarthritis, Secondary Osteoporosis.
APPENDIX S

Definition of Variables in Logistic Regression Analyses

Outcome #1: **Whether men and women started or increased calcium intake (Yes or No)**

Study Group: Eligible men and women who completed baseline and follow-up study questionnaires \( n = 188 \)

**Primary Independent Variables**

1) BMD screening results reported as T-score level (lowest T-score level for measured BMD of three measured sites – left and right femoral neck, and lumbar spine) based on WHO definitions:
   a.) osteoporosis (T-score ≤ -2.5)
   b.) osteopenia (T-score < -1.0 to > -2.5)
   c.) normal (T-score ≥ -1.0)

2) Received theory-based osteoporosis education intervention (yes or no)

**Secondary Independent Variables**

- Age (years)
- Age (50-64, > 65 years)
- Gender (male or female)
- Body weight (kg)
- Dietary calcium intake (mg) at baseline (per 100 mg/day increase)
- Calcium supplement intake (yes or no) at baseline
- Total calcium intake (< 1,200 mg or ≥1,200 mg) at baseline
- Fracture history after 40 years of age (yes or no)
- Family history of adult fracture (yes or no)
- Cigarette smoking status (current)
- Number of current medications (prescription and over-the-counter, group mean)
- Education (high school or less, college/university or higher)
- Household income (< $30,000 or ≥ $30,000)
- Marital status (divorced/separated/widowed, never married/single, married/common-law)
- Routine medical care (more than once per year)
- Follow-up discussion of BMD screening results with a HCP (yes or no)
Outcome #2: Whether men and women started or increased vitamin D intake (Yes or No)

Study Group: Eligible men and women who completed baseline and follow-up study questionnaires ($n = 188$)

Primary Independent Variables

1) BMD screening results reported as T-score level (lowest T-score level for measured BMD of three measured sites – left and right femoral neck, and lumbar spine) based on WHO definitions:
   a.) osteoporosis (T-score ≤ -2.5)
   b.) osteopenia (T-score < -1.0 to > -2.5)
   c.) normal (T-score ≥ -1.0)

2) Received theory-based osteoporosis education intervention (yes or no)

Secondary Independent Variables

- Age (years)
- Age (50-64, > 65 years)
- Gender (male or female)
- Body weight (kg)
- Dietary vitamin D intake (IU) at baseline (per 1 IU increase)
- Vitamin D supplement intake (yes or no) at baseline
- Total vitamin D intake (< 800 IU, ≥ 800 IU) at baseline
- Fracture history after 40 years of age (yes or no)
- Family history of adult fracture (yes or no)
- Cigarette smoking status (current)
- Number of current medications (prescription and over-the-counter, group mean)
- Education (high school or less, college/university or higher)
- Household income (≥ $30,000 or < $30,000)
- Marital status (divorced/separated/widowed, never married/single, married/common-law)
- Routine medical care (more than once per year)
- Follow-up discussion of BMD screening results with a HCP (yes or no)
Outcome #3: Whether men and women start or increase physical activity (Yes or No)

Study Group: Eligible men and women who completed baseline and follow-up study questionnaires ($n = 188$)

Primary Independent Variables

1) BMD screening results reported as T-score level (lowest T-score level for measured BMD of three measured sites – left and right femoral neck, and lumbar spine) based on WHO definitions:
   a.) osteoporosis (T-score ≤ -2.5)
   b.) osteopenia (T-score < -1.0 to > -2.5)
   c.) normal (T-score ≥ -1.0)

2) Received theory-based osteoporosis education intervention (yes or no)

Secondary Independent Variables

- Age (years)
- Age (50-65, > 65 years)
- Gender (male or female)
- Body weight (kg)
- Fracture history after 40 years of age (yes or no)
- Family history of adult fracture (yes or no)
- Level of physical activity (high, moderate, low)
- Physical activity score (per one unit increase)
- Vitamin D supplement intake (yes or no) at baseline
- Calcium supplement intake (yes or no) at baseline
- Cigarette smoking status (current)
- Number of current medications (prescription and over-the-counter, group mean)
- Education (high school or less, college/university or higher)
- Household income ($\geq$ $30,000$ or $< $30,000)
- Marital status (divorced/separated/widowed, never married, married/common-law)
- Routine medical care (more than once per year)
- Follow-up discussion of BMD screening results with a HCP (yes or no)
Outcome #4: Whether men and women initiated recommendations for new osteoporosis drug treatment (Yes or No)

Study Group: Eligible men and women who completed baseline and follow-up study questionnaires and who discussed screening results with their HCP (n= 103)

Primary Independent Variables

1) BMD screening results reported as T-score value (lowest T-score value for measured BMD of three measured sites – left and right femoral neck, and lumbar spine)

2) Received theory-based osteoporosis education intervention (yes or no)

Secondary Independent Variables

- Age (years)
- Age (50-64, > 65 years)
- Gender (male or female)
- Fracture history after 40 years of age (yes or no)
- Family history of adult fracture (yes or no)
- Number of current medications (prescription and over-the-counter, group mean)
- Education (high school or less, college/university or higher)
- Routine medical care (more than once per year)
- Gender of HCP (male or female)
- Length of relationship with HCP (years)